

Exhibit I

Shelby F. Thames, Ph.D.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., MASTER FILE NO.
PELVIC REPAIR SYSTEM 2:12-MD-02327
PRODUCTS LIABILITY LITIGATION
MDL 2327

JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

GENERAL DEPOSITION OF
SHELBY F. THAMES, Ph.D.

Taken at Butler Snow
1020 Highland Colony Parkway, Suite 1400,
Ridgeland, Mississippi,
on Thursday, March 24, 2016,
beginning at approximately 8:10 a.m.

AMY M. KEY, RPR, CSR
Notary Public

A P P E A R A N C E S

REPRESENTING THE PLAINTIFFS:

DOUGLAS C. MONSOUR, ESQ.

KATY KROTTINGER, ESQ.

Monsour Law Firm

404 North Green Street

Longview, Texas 75601

(903) 758-5757

doug@monsourlawfirm.com

katy@monsourlawfirm.com

JACOB W. PLATTENBERGER, ESQ. (Via Telephone)

Tor Hoerman Law LLC

101 West Fulton Street

Chicago, Illinois 60661

(618) 656-4400

jake@THLawyer.com

MICHAEL H. BOWMAN, ESQ.

Wexler & Wallace LLP

55 West Monroe Street, Suite 3300

Chicago, Illinois 60603

(312) 346-2222

mhb@wexlerwallace.com

SHEILA M. BOSSIER, ESQ. (Via Telephone)

Bossier & Associates, PLLC

1520 North State Street

Jackson, Mississippi 39202

601.352.5450

sbossier@bossier-law.com

REPRESENTING THE DEFENDANTS:

CHAD R. HUTCHINSON, ESQ.

Butler Snow LLP

1020 Highland Colony Parkway, Suite 1400

Ridgeland, Mississippi 39157

(601) 985-5711

chad.hutchinson@butlersnow.com

Shelby F. Thames, Ph.D.

1	TABLE OF CONTENTS	
2		PAGE
3	Title Page.....	1
4	Appearance Page.....	2
5	Table of Contents.....	3
6	Exhibit Page.....	4
7	Stipulation Page.....	5
8		
9		
10	*****	
11	EXAMINATION OF SHELBY F. THAMES, Ph.D.	
12		
13	By Mr. Monsour.....	6
14	By Mr. Hutchinson.....	138
15	Further By Mr. Monsour.....	140
16	Further By Mr. Hutchinson.....	141
17		
18	Certificate Page.....	142
19	Signature Page.....	143
20		
21		
22		
23		
24		
25		

Shelby F. Thames, Ph.D.

1	*****	
2	E X H I B I T S	
3		PAGE
4		
5	Exhibit No. 1, Expert Report of Shelby F.	
6	Thames, PhD, March 1, 2016.....	6
7	Exhibit No. 2, Excerpt from Article, "The Reaction	
8	of Formaldehyde with Proteins".....	19
9	Exhibit No. 3, Excerpt from Article, "Reaction of	
10	Formaldehyde with Proteins".....	19
11		
12	Exhibit No. 4, Article, "Chemical and	
13	Morphological Analysis of Explanted Polyurethane	
14	Vascular Prostheses: The Challenge of Removing	
15	Fixed Adhering Tissue.....	32
16	Exhibit No. 5, As Exemplar, Amended Case-Specific	
17	Report of Shelby F. Thames, PhD, Joyce	
18	Justus v. Ethicon, March 22, 2016.....	68
19	Exhibit No. 6, Hand-Drawn Diagram of Cross-Section	
20	of Prolene Fiber, "Hypothetical".....	94

Shelby F. Thames, Ph.D.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

S T I P U L A T I O N

It is hereby stipulated and agreed by
respective attorneys of record, that this
deposition may be taken at the time and place
hereinbefore set forth, by AMY M. KEY, Court
Reporter and Notary Public, pursuant to the Rules;
That the formality of reading and
signing is specifically RESERVED;
That all objections, except as to the
form of the questions and the responsiveness of
the answers, are reserved until such time as the
deposition, or any part thereof, may be used or
sought to be used in evidence.

Shelby F. Thames, Ph.D.

1 (EXHIBIT NO. 1 PRE-MARKED.)

2 SHELBY F. THAMES, Ph.D.,

3 having been first duly sworn,

4 was examined and testified as follows:

5 EXAMINATION

6 BY MR. MONSOUR:

7 Q. Good morning.

8 A. Good morning.

9 Q. Would you please state your name?

10 A. Shelby F. Thames, T-H-A-M-E-S.

11 Q. And, Dr. Thames, what do you do for a
12 living?

13 A. I am a polymer scientist at the University
14 of Southern Mississippi. I initially retired a few
15 years ago, but I'm back working half time. We do
16 research and study the area of polymers.

17 Q. What type of polymers would you say you
18 specialize in?

19 A. Well, there are multiple types of polymers
20 that we specialize in. There are heterocyclic type
21 polymers in the sense that they have multiple type
22 atoms, and then we also do work in molecules that
23 contain, essentially, hydrogen and carbon. But,
24 generally, I've been there long enough, I've done a
25 lot of -- most every -- any kind of polymer we've

1 got.

2 Q. What's been marked as Exhibit 1, I think
3 you have a copy in front of you, --

4 A. Yes, sir.

5 Q. -- is your expert report.

6 Do you see that?

7 A. I do, sir.

8 Q. I'm just going to read from this one.

9 Mine has some notes on it.

10 But if we look at your report, it is -- it
11 looks like it's 128 pages long; is that correct?

12 A. I believe so.

13 Q. Give me an idea, Dr. Thames, how did this
14 report come to be?

15 A. I wrote it.

16 Q. Did you write every word of it?

17 A. Yes, sir.

18 Q. Now, if I look at it -- and you've done
19 something which I really appreciate. I've already
20 complimented you on your writing, but you did
21 something else that I also appreciate. You
22 footnoted it, --

23 A. Yes, sir.

24 Q. -- which helps me in looking at things.

25 A. Yes, sir.

1 Q. In the footnotes -- it looks like you have
2 344 footnotes in your report. Does that seem
3 accurate?

4 A. That seems about right.

5 Q. In those footnotes, Dr. Thames, there are
6 a lot of textbooks. There are a lot of articles. I
7 think there might even be some depositions.

8 The question that I have is, with regard
9 to the scientific articles or textbooks that you
10 picked to put in here, how did you select those?

11 A. Well, there were specific issues that
12 during the course of writing this report that I felt
13 needed a reference. And there's so many people that
14 will write and assume that whatever they write is
15 true and accurate, and I like to reference materials
16 as I see fit.

17 Q. Okay.

18 A. So then we begin to look for a reference,
19 some of which I knew pretty much exactly where to
20 go --

21 Q. Okay.

22 A. -- and others are the topical areas. So
23 that's how I developed the bibliography.

24 Q. Would it be a situation where you would
25 have an idea of, I want to write this, write it, and

1 then go get some sort of a footnote for support for
2 it?

3 A. I know this is -- in my mind, I know this
4 is true, but I want some verification of this in
5 addition to what I believe so that others can read
6 it and say, well, other people believe that too and
7 here is reference to that work.

8 Q. For the articles and textbooks that you
9 cite, do you believe that those are reliable sources
10 that we can look to to be, you know, good, solid
11 scientific articles and textbooks?

12 A. Well, for the most part, yes. We talk
13 about peer reviewed articles, and I think some of
14 them are really good, and I think some of them are
15 average, and I think some of them are fairly poor.

16 Q. Okay. And I want to ask this in a general
17 way without having to go through it. But if you
18 cited an article or a textbook as authoritative in
19 here or as a footnote, you believed it was a
20 reliable and authoritative textbook, unless you were
21 citing it in a way to talk about how it was
22 incorrect. Is that a fair statement?

23 A. Well, I think what you're asking me, so I
24 make sure I understand it, is that it's either pro,
25 in response to my feelings, or not pro. And I think

1 there's not much in between, is there?

2 Q. I agree.

3 A. Yes, sir.

4 Q. So let me make sure we are on the same
5 page because my question was kind of sloppy, as
6 sometimes they tend to be.

7 If you've cited an article just as a
8 reference and you're talking about the weaknesses of
9 it, you're obviously not citing it as authoritative
10 or reliable. You are criticizing it.

11 Fair enough?

12 A. Yes, sir.

13 Q. But when you are citing a reference for
14 support for one of your propositions, you believe
15 those are reliable and authoritative?

16 A. Yes, sir, and in the main. Yes, sir.

17 Q. And tell me what you mean by "in the
18 main."

19 A. Well, I can't sit here as I talk to you
20 today and remember every word or every paragraph
21 that was in an article that I might have read two
22 years ago or three years ago, but I wouldn't have
23 cited it if I didn't think it was appropriate to do
24 so.

25 Q. Okay. That's fair enough.

1 As far as your overall -- it appears to me
2 from reading your report that most of your opinions
3 seem to flow back to one basic premise that differs
4 from other expert opinions in this litigation. Is
5 that a fair statement?

6 MR. HUTCHINSON: Object to form.

7 THE WITNESS: Well, let me phrase that
8 in a way I think of it, if you don't mind my
9 doing that.

10 BY MR. MONSOUR:

11 Q. That's okay.

12 A. Obviously, the plaintiffs' experts'
13 opinions are, in my opinion, incorrect. And they
14 flow back to -- one simple thing for me is that
15 Prolene is a very good polymer for its use. I
16 believe it is about as good as you can get, as I've
17 written in this document, for the use that it's been
18 specified for.

19 It has been, in my opinion, maligned in
20 the sense that it has been referred to as being not
21 a good system, not fit for use, so forth. And
22 there, in my opinion, are no solid scientific facts
23 that support this contention.

24 Now, there's a lot of words and there's a
25 lot of "I think" or "may be," but there are no solid

1 scientific facts that support that contention.

2 Q. Okay. So let's talk about -- let's talk
3 about some of these theories. And what I was
4 getting at -- this is -- okay. I don't talk like a
5 polymer chemist because I'm not one. I try and talk
6 like just a regular, everyday language kind of guy.

7 So my question is, the one position that
8 it seems to me that a lot of your opinions go back
9 and that everything seems to flow from is the issue
10 of degradation on the surface.

11 You are saying that surface degradation of
12 the Prolene does not take place. Instead, what's
13 going on is a chemical reaction that is forming some
14 sort of an outer layer, and that is what the other
15 guys are seeing.

16 Am I close?

17 A. Yes, sir, very. You're getting warm, as
18 we say.

19 Q. Tell me where I'm -- restate it so it's
20 100 percent accurate in regular people words.

21 A. Well, first of all, in regular people
22 words, I think you've done a very good job.

23 Q. Thank you.

24 A. But being specific, when explants are
25 taken in the surgery suites, almost -- I'm not

1 there, so I can't say 100 percent that they are.

2 But in the vast majority of cases, they are put into
3 formaldehyde. And that is to preserve them so that
4 the tissue doesn't rot.

5 When they do that, formaldehyde is a
6 highly reactive chemical, and it begins to react
7 instantly with the proteins of the flesh. And the
8 flesh is all around the explant at that time. And,
9 in particular, collagen is surrounding the explant
10 itself as the first coating to be applied to a
11 Prolene explant. Because once it's in the body,
12 collagen rushes to it, forms a layer, and then all
13 the other body parts, the flesh, comes in and it
14 sees collagen.

15 Well, collagen reacts with formaldehyde,
16 as does the other flesh, with the proteins. If
17 there's a protein there, formaldehyde will react
18 with it. And it produces a hard, brittle, porous,
19 insoluble product.

20 And the reason that they use formaldehyde
21 is to, number one, preserve the flesh. But in terms
22 of farther experimentation, if someone is going to
23 prepare a slide for a histology, for instance, and
24 they use a microtome -- are you familiar with a
25 microtome?

1 Q. Yes, sir.

2 A. In order to use a microtome, they want
3 that piece of material they're going to cut to be
4 firm so that when they slice it across here, it
5 doesn't do this (slaps hand over on table).

6 Q. Right. It's got to hold it in place.

7 A. It's got to hold it in place.

8 So the hold in place or the shield or the
9 armor is the coating system or composite. I can
10 call it a composite or a coating. It's a coating
11 because it adheres tenaciously to the Prolene, and
12 it's a composite because it's thick.

13 So that way, in that regard, when the
14 microtome comes across, it holds it in the main,
15 steady, and you can get a slice. If it doesn't do
16 that, you can't get a 3- to 4-micron slice to make a
17 slide from.

18 Q. Okay. I generally understand what you're
19 saying. Now, I want you to understand one thing,
20 though. When I say we have to talk like regular
21 people, --

22 A. Yes, sir.

23 Q. -- there's four lawyers in this room.

24 A. Yes, sir.

25 Q. In order of who understands this stuff the

1 best, there's one and two right there (indicating).
2 I'm not going to say which one is one and which one
3 is two.

4 MR. HUTCHINSON: For the record, he
5 pointed at defense counsel first.

6 BY MR. MONSOUR:

7 Q. There's those two over there, and then
8 there's number three, and here is four (indicating
9 himself).

10 A. Okay.

11 Q. And here is why today can be a little odd,
12 because number four is asking the questions on these
13 issues. So we're going to have to go real slow.

14 A. Was I too fast?

15 Q. No, no. You were good. I'm just kind of
16 giving you an idea of the pecking order. So if
17 you've talked to Chad about some stuff and he's
18 like, "Yeah, got it, got it, got it," I'm not that
19 way. I'm a little slower.

20 A. Okay.

21 Q. But that's okay.

22 A. If I can, I will go back and add to the
23 question you asked me.

24 Q. Yes.

25 A. The plaintiffs' experts have ignored the

1 fact that that protein-formaldehyde layer forms
2 and/or exists. And, as a result, I have very
3 different opinions than they do about the chemistry
4 that's going on. And I would quote you my by-line
5 so that you'll know where I'm coming from for the
6 next several days. It's all in the chemistry,
7 period.

8 Q. Okay. Good, good.

9 Now, one of the things that you have done
10 when I look at that, when you talk about the
11 chemistry, you have -- I think at some point in time
12 you have referenced some science from a long way
13 back, from the '40s, and you've said, "Hey, this
14 isn't new. This is back in the '40s, and here's an
15 article," right?

16 A. Yes.

17 Q. And there's some guy who wrote it and he's
18 got a hyphenated name, right?

19 A. Yes.

20 Q. See, I remember some stuff. Okay. So
21 there's articles from the 1940s and --

22 A. '49, to be specific.

23 Q. 1949. And those are the articles that
24 basically set up the chemistry, the foundation of
25 the chemistry that your opinions flow from?

1 A. Well, yes, in the sense that that science
2 has been known for 50, 66 years, and it has been
3 ignored here. And it was developed primarily for
4 the reason that you and I are talking about, where
5 those individuals needed a way to look at tissue.
6 They needed a way to make slides. And so it's been
7 in the literature.

8 As a matter of fact, Dr. Lester has
9 written a manual that's in almost all operating
10 suites. And in that manual -- and that's referenced
11 in my report. Susan Lester has written a manual,
12 and in that manual she talks about the fixation
13 process.

14 Now, I don't know if my lawyer is going to
15 fuss at me about going into this lecture we're
16 having, but this is the only way I know to try to
17 help you understand where I'm coming from today.
18 And that's what you want me to do, right?

19 Q. Yeah, yeah.

20 A. Fixation -- and there's another thing in
21 chemistry. You have to listen to the words. This
22 is called fixation. That reaction is called, by the
23 general -- by the M.D.s and the pathologists and so
24 forth, fixation.

25 What does that mean? It means holding

1 something in place.

2 Q. Okay. Got it.

3 A. Just like I described to you a moment ago
4 when I talked about forming the hard shell around
5 the fiber, I took my glass of water and put my hand
6 around it like I'm holding this bottle of water in
7 place.

8 Q. Right.

9 A. So the fixation process was developed to
10 hold things in place and to preserve the flesh. I'm
11 sure if you took high school biology you've run into
12 contact with formaldehyde, more than likely.

13 So that's just been known for 60 years.
14 Why aren't some people recognizing it in the
15 science?

16 Q. Okay. Let me ask you some questions about
17 that.

18 Now, your theory is our guy is not too
19 sharp, ignoring 66 years of chemistry that these
20 people have written about, that Dr. Lester has
21 talked about, and it's well-known in the scientific
22 community, right?

23 A. Yes, sir.

24 Q. Wouldn't it be a little bit of a stretch
25 to think that all these people on our side are

1 missing such a basic point?

2 MR. HUTCHINSON: Object to form.

3 THE WITNESS: You know, I really don't
4 know why they're missing it, but I do know
5 they are, but I can't tell you why.

6 BY MR. MONSOUR:

7 Q. So let me ask -- let's go back to some of
8 that.

9 Can you give me some of those articles?

10 MS. KROTTINGER: (Hands over documents.)

11 (EXHIBIT NO. 2 MARKED.)

12 BY MR. MONSOUR:

13 Q. So, Dr. Thames, I'm going to mark this as
14 Exhibit No. 2. Your report was 1. Here's Exhibit
15 No. 2. I think this is one of the articles you
16 cite. And I was right. There's a hyphen. It's
17 Heinz Fraenkel-Conrat. There's the spelling.

18 And it's an article, "The Reaction of
19 Formaldehyde with Proteins," and this is part 7. I
20 think this is the one you cite. I don't know if I
21 have an extra one.

22 Is that the one you're talking about?

23 And here's another one I'll show you,
24 Dr. Thames. This one is No. 3.

25 (EXHIBIT NO. 3 MARKED.)

1 BY MR. MONSOUR:

2 Q. This is one that kind of, in my mind,
3 speaks -- or at least in her mind speaks a little
4 more specifically. It's another one of the articles
5 in a series of this, Exhibit 3. It's written by the
6 same author, Fraenkel-Conrat.

7 A. Yeah, sure. Both of these articles speak
8 to the science that I'm referring to.

9 Q. So here's one of the questions that I
10 have. In your report on page 17, you have an
11 equation. And that equation explains what you're
12 talking about, correct?

13 A. Yes, sir.

14 Q. And you got it from Fraenkel-Conrat, as
15 you have referenced?

16 A. Well, that -- I put that together. I used
17 his science to reference it. But as a polymer
18 scientist, I've known this reaction occurred for
19 years. So I put it together myself based on the
20 science I understand and know and as referenced by
21 these papers.

22 Q. So if you look at the equation that you
23 have on page 17 of your report, basically what it
24 shows is it's a protein plus a formaldehyde goes to
25 create this cross-linked protein-formaldehyde

1 polymer, correct?

2 A. Yes, sir. And this is just one example.
3 This is from an amide functional hydrogen. There
4 can be amines that are there. This is just to give
5 you an overall view of this equation. But it's
6 amines or amide functionality that cross-link with
7 formaldehyde to give you the condensed polymer and
8 the formation of the hard shell.

9 Q. And I guess what I'm getting at is, if you
10 look in these articles, they actually call it pretty
11 much the same -- they refer to it as a cross-linking
12 in the 1948 or '49 article, correct?

13 A. Yes, sir.

14 Q. And that's what you're referring to it as,
15 correct?

16 A. Yes, sir.

17 Q. Now, one of the questions that -- if we
18 look at this group, it talks about to have this
19 chemical reaction take place, you need to have the
20 proteins, the formaldehydes, but you need to have --
21 one of the things that's necessary is an amino
22 group. That's talked about in the article, correct?

23 A. Yes.

24 Q. But you don't have an amino group in your
25 equation.

1 A. This is an amide group, which is the
2 derivative that I just stated. But there are also
3 amino group functionalities in the proteins. Those
4 groups will react exactly the same way as this amide
5 type functionality that I've shown you.

6 Q. But I guess my question is, is your
7 cross-linking that you have, is this that you're
8 explaining here, is this -- is there anything with
9 your equation that's different than what
10 Dr. Fraenkel-Conrat was talking about 66 years ago?

11 Are you pretty much directly on point with
12 him?

13 A. Yes, sir.

14 Q. All right. And has this chemistry ever
15 changed?

16 A. No, sir.

17 Q. Chemistry is chemistry is chemistry is
18 chemistry?

19 A. That's it.

20 Q. Now, one of the things that you have
21 talked about is the strength of this cross-linked --
22 you call it a --

23 MR. MONSOUR: Hold on. I want to get
24 him and I on the same page.

25 BY MR. MONSOUR:

1 Q. What you're calling -- see, she wants to
2 tell me it's a methylene-something group.

3 A. She's right.

4 Q. She might as well be speaking Chinese to
5 me. I don't know what that is. I'm going to call
6 it the stuff on the outside.

7 As far as the stuff that's on the outside,
8 basically what you're saying is that's not degraded
9 polypropylene. That's not degraded Prolene. That
10 is this protein-formaldehyde mixture/combination
11 that forms this cross-linked protein-formaldehyde
12 polymer, right?

13 A. In your terminology, yes. This is the
14 composite, the material that's formed around the
15 fiber by virtue of formaldehyde reacting with
16 proteins.

17 Q. Now, in the literature -- and you have
18 referenced -- you've said this is the science. This
19 has been the science for 66 years. We've known it.
20 And probably, in truth, they knew it before this.

21 The question that I have is, since that
22 time, over time, has there been a known way to clean
23 these pieces of polypropylene, or whatever this
24 cross-linked polymer forms on, so that we can look
25 at the underlying prosthesis?

1 A. The material that I read -- and people
2 have tried a variety of techniques. The proposition
3 that I was faced with is you have these explants.
4 You want to look at the explants, and you do not
5 want to harm them. And "them" being the fiber.
6 When I say an "explant," I'm primarily talking about
7 fiber, okay, the Prolene fiber. You don't want to
8 harm that so that when you finally do get everything
9 removed from the fiber you haven't damaged it in the
10 process of doing that.

11 Q. Okay.

12 A. So the approach that we took in cleaning
13 this was one which -- it goes back to this equation
14 that you're pointing out on page 17.

15 Q. Okay.

16 A. If you'll notice, this equation, it shows
17 the protein plus the formaldehyde. And, normally,
18 in a chemical reaction you'll have a yields sign
19 with an arrow pointing in one direction. But if you
20 notice something about these arrows, they go in both
21 directions, meaning that is an equilibrium reaction.

22 So you've got -- assume that this one
23 arrow is going in both directions, as it shows here.
24 So if I want to clean this material and I want to
25 get back to the fiber that's encased by this product

1 right here, and I'm pointing to the protein and the
2 formaldehyde composite that would form, then I would
3 add water and heat and the reaction reverses.

4 And so I've taken a very mild set of
5 circumstances chemically speaking, reversed the
6 reaction, used a little sodium hypochlorite to get
7 rid of some of the flesh to get to a fiber that is
8 as pristine, in my view, as you could ever have
9 coming from -- as an explant to be analyzed.

10 So I have an explant that has not been
11 damaged in any way. And what I look at is what was
12 there in the body.

13 Q. But if I look at your cleaning protocol,
14 it seems like there's a lot more steps involved than
15 just a little water and a little heat.

16 A. Oh, there is. The steps are there to
17 ensure that we ultimately get all the material off
18 the explant. It's very difficult. Because the
19 adhesion that takes place between the proteins and
20 the explant itself is tenacious. It's a very strong
21 bond.

22 So we've got to break through that crust
23 of composite material. We've got to break through
24 the armor and finally get to remove all of the
25 proteins, if that's possible.

1 Q. So in light of the fact that this bond
2 that forms is so tenacious, would the tenacity of
3 such a bond have been known to scientists for
4 decades?

5 MR. HUTCHINSON: Object to form.

6 THE WITNESS: It should have been.

7 BY MR. MONSOUR:

8 Q. And the reason -- I'm going to ask you a
9 few questions that sound kind of like state-of-mind
10 questions. But you've told me that our people have
11 ignored it, which is kind of a state-of-mind
12 comment, so I'm going to kind of come back with a
13 few state-of-mind questions.

14 A. Sure.

15 Q. Whether they're admissible or not, who
16 knows?

17 But my point is, was it well understood in
18 the scientific community, in your opinion, that
19 these bonds were tenacious?

20 A. Yes, sir.

21 Q. And was it well known that you had to take
22 that into account when you were cleaning prosthesis
23 that would have this coating, this cross-linked
24 protein-formaldehyde polymer coating on top of it?

25 MR. HUTCHINSON: Object to form.

1 THE WITNESS: Would you restate that,
2 please?

3 BY MR. MONSOUR:

4 Q. Yeah. Was it well known in the scientific
5 community that when cleaning the cross-linked
6 protein-formaldehyde polymer that would form on the
7 outside, that you would need to take into account
8 the tenacity in order to get -- to remove everything
9 that had formed on the outside of an implant?

10 MR. HUTCHINSON: Same objection.

11 THE WITNESS: It should have been.

12 BY MR. MONSOUR:

13 Q. So what you're saying is basically, as I
14 understand it, what you're saying is, "I'm the
15 mainstream guy here. I'm looking at all this --
16 everything I'm telling you has been known for
17 six-and-a-half decades. You guys have just ignored
18 it," right?

19 A. Well, either they ignored it or they
20 didn't know about it. I mean, I don't know what
21 they -- I don't know why they don't talk about it,
22 but that's the case. It's irrefutable that this
23 happens.

24 Q. But I guess my point is, I mean, if you're
25 telling me this is common knowledge and it's well

1 known -- and you've got two articles here from the
2 '40s. And it looks like it's a series of at least
3 seven, so this isn't something that came out two
4 weeks ago. If it's so well known, how could so many
5 scientists have missed it?

6 MR. HUTCHINSON: Form.

7 THE WITNESS: Well, a lot of people have
8 missed it, and I believe that's because they
9 aren't looking at the fundamental chemistry.
10 And the people who have been looking at this
11 particular issue are not necessarily
12 chemists. A lot of them have medical
13 backgrounds. A lot of them are engineers.
14 And they may not be that well versed in basic
15 organic chemistry.

16 BY MR. MONSOUR:

17 Q. Do you know Dr. Jimmy Mayes?

18 A. I do.

19 Q. Do you know him well?

20 A. Well, I would say, yes, I know him pretty
21 well.

22 Q. He's pretty competent in chemistry,
23 wouldn't you say?

24 A. I would definitely say so.

25 Q. He's a nice guy, wouldn't you agree?

1 A. Absolutely. I like him.

2 Q. One of the questions that I would like to
3 go over with you is, in light of the fact that this
4 bond, the tenacious bond that forms, as you have
5 described, and it's been known about for years, I
6 would assume that scientists that understand this
7 bond have come up with ways of cleaning these
8 implants to weaken the bond so everything -- this
9 entire polymer that you describe would go away.

10 Is that fair, that over the years people
11 have come up with some sort of a cleaning protocol
12 for that?

13 MR. HUTCHINSON: Object to form.

14 THE WITNESS: I didn't find one. But I
15 did find some articles, and I referenced it
16 in my report here, of Dr. Robert Guidoin. He
17 wrote an article, and the main context of
18 that article dealt with the difficulty in
19 cleaning explants.

20 BY MR. MONSOUR:

21 Q. Okay.

22 A. And he talked about the fact that you need
23 to be very careful because you'll have -- you
24 probably would have to use harsh chemicals and so
25 forth.

1 So that tells me -- and I think that was
2 in the '80s, the late '80s -- that he, himself, had
3 missed this rather simple chemistry and was not
4 giving consideration to this bond.

5 Q. So you think Dr. -- is it pronounced
6 "Gee-don"?

7 A. I'm really not sure.

8 Q. I've been saying "Gwe-doin" or whatever.
9 But we know who we're talking about?

10 A. I think we're talking about the same
11 gentleman.

12 Q. So I want to go back through your
13 questions. Because when I look at your report, it
14 seemed like you were citing Dr. Guidoin as an
15 authority. Are you telling me you were not?

16 A. Well, I'm citing him to show that he, as
17 an authority -- he's been mentioned in this
18 litigation on several issues --

19 Q. Right.

20 A. -- and providing explants and so forth to
21 Ethicon and so forth, and he, himself, is citing how
22 difficult it is to remove this material and to
23 clean -- let's put it this way -- to clean the
24 explants.

25 Q. Okay.

1 A. And so my thought -- since I'm testifying
2 and I don't ask questions, but my thought can be in
3 the form of a question, why didn't he know this?

4 Q. Okay.

5 A. I mean, it's 1988. He knows there's a
6 reaction going to on. He knows that the explants
7 are covered. He says, "This stuff here is difficult
8 to get off." And I'm thinking, "Why don't you go
9 back to the fundamental chemistry of how it was put
10 there in the first place?", i.e., the reaction of
11 flesh when you drop it in formaldehyde to preserve
12 it and to fix it.

13 Q. Where do you find that Dr. Guidoin is
14 saying it's hard to get off and we don't know? Is
15 it this?

16 A. Well, let me look at your article here.

17 Q. What I've highlighted is the first part of
18 the quote that you have on page 16 and 17 of your
19 report.

20 A. Yes, sir. Do you mind if I cite the title
21 of this article?

22 Q. Absolutely.

23 A. The article is from a journal called
24 "Biomaterials," Volume 17. It was written in 1996.
25 The title is "Chemical and Morphological Analysis of

1 Explanted Polyurethane Vascular Prostheses."

2 Q. Here, let's do this. I've got a clean
3 copy. I'm going to mark it, and I'll give you this
4 one.

5 (EXHIBIT NO. 4 MARKED.)

6 BY MR. MONSOUR:

7 Q. Here is No. 4. I'll give you this one,
8 and that's for you, and you give me that one back.

9 A. And continuing that, after the colon, it
10 says, "The challenge of removing fixed adhering
11 tissue."

12 Now, it's important. The challenge,
13 meaning it's difficult of removing fixed, i.e., the
14 fixation process -- I've talked about adhesion,
15 adhering tissue.

16 Q. Now, the substances that he's talking
17 about, in all fairness, he's not talking here about
18 removing from polypropylene. I think he's talking
19 about polyurethane.

20 Does that matter?

21 A. No, sir. Not if it's in flesh, it doesn't
22 matter.

23 Q. So would the same thing happen to a
24 polypropylene implant as a polyurethane implant?

25 A. When you say "the same thing," if a

1 polyurethane implant/explant were in the body and
2 had flesh on it and had been preserved in
3 formaldehyde, yes, sir. It doesn't matter what
4 you're cleaning. If that object comes out and goes
5 into formaldehyde, there's a fixation product that
6 forms around it.

7 Q. So here's -- again, we're going to talk
8 about -- this is me talking as a regular person.
9 Your theories in this litigation as to the coating
10 that's on the outside of the Prolene isn't so much
11 dependent upon the Prolene. It's more dependent
12 upon the flesh and the formaldehyde bonding; is that
13 right?

14 A. Well, that's the two components that
15 produce the encasement around the Prolene or
16 polyurethanes or whatever.

17 Q. Right, right. But am I right? I mean,
18 that's basically what you're saying.

19 Whether we make the implant polypropylene
20 or polyurethane or poly-whatever, what you're
21 talking about is the reaction that's going on on the
22 outside that forms between the flesh and the
23 formaldehyde?

24 A. On the surface of whatever you would have
25 in flesh.

1 Q. And so if you can get that
2 flesh-formaldehyde combination off, underneath you
3 would have pristine material?

4 A. Yes, sir.

5 Q. Okay.

6 A. If you get it off without damaging the
7 object that you're looking to evaluate and determine
8 if it's --

9 Q. Okay. And you don't quote that, but
10 that's the next thing that's listed in this article.
11 If we look, your quote says -- and I'll read your
12 quote for anybody that's reading this deposition
13 that's not looking at it.

14 But your quote says, "In order to study
15 the surface chemistry of explanted prosthesis, it is
16 necessary to remove all the tissue that may have
17 grown over and within the prosthetic structure,"
18 correct?

19 A. Yes, sir.

20 Q. "In the event that the explant has been
21 treated with a fixative agent after retrieval, such
22 as formaldehyde or glutaraldehyde, the tissue will
23 be cross-linked. And the only effective way of
24 completely removing it is to use hydrolytic
25 chemicals," correct?

1 A. Correct.

2 Q. "Depending on the degree of cross-linking,
3 strong chemicals and/or extreme hydrolysis
4 conditions may be required," correct?

5 A. That's what it says, yes, sir.

6 Q. And then if we continue -- that's where
7 your quote stops, but I want to read a little
8 further because I think it's what you just told me.

9 "Under these circumstances, caution should
10 be exercised when using such severe chemical
11 conditions because of the risk of modifying the
12 inherent chemical and physical structure of the
13 biomaterial," correct?

14 A. Correct.

15 Q. And that's what I think, I think, you just
16 told me was, we want to take the outer layer off,
17 but we don't want to go so far as we damage the
18 implant.

19 A. Absolutely.

20 Q. Okay. Good. We're on the same page.
21 Sometimes I read stuff and I don't know that what
22 I'm reading is what I think I'm reading, so I'm at
23 least on the right page.

24 Now, here's one of the questions that I
25 have. It says here, "In the event... The only

1 effective way of completely removing it is to use
2 hydrolytic chemicals," right?

3 A. That's what he says, yes.

4 Q. Do you agree with that statement?

5 A. I do.

6 Q. So what is a hydrolytic chemical?

7 A. Water. Something to hydrolyze or break
8 apart a chemical bond with water. That's one thing.

9 Q. Okay.

10 A. Acids could be in water, in aqueous
11 solutions. But water, in my opinion, is the very
12 best one to use, and that's what we used.

13 Now, contrary to what Dr. Guidoin
14 commented, we didn't use dangerous chemicals. We
15 didn't use chemicals that would affect the structure
16 of the fiber. We used a very mild set of
17 circumstances, i.e., water. It's not a strong acid.
18 It's not a strong base. It's a hydrolytic chemical,
19 but it's water.

20 Because of the reaction that I showed you,
21 this reaction I'm pointing to on page 17, water is
22 your hydrolytic chemical, and the reaction goes this
23 way. Water reacts with the cross-linked methylene
24 bridge, breaks it apart, goes back and gives you --
25 regenerates formaldehyde and the protein material

1 that's -- the protein.

2 Q. So this equation, this bond that forms as
3 described on page 17 of your report, in your
4 opinion, can be broken with hydrolytic chemicals?

5 A. No, that's not exactly the way I stated
6 this.

7 Q. Okay. You just lost me then. I was doing
8 so good.

9 A. I'm going to go back and redo this, redo
10 my statement.

11 If you look at the equation on page 17,
12 you see a protein that's going to react with -- and
13 that's plus -- formaldehyde. And then you have an
14 equilibrium arrow that says it produces
15 protein-methylene bond bridge. It cross-links it.
16 That's a fixation process. Then when that has
17 happened, the proteins have been fixed.

18 Q. Okay.

19 A. And if you envision the fiber as being
20 this glass of water, they are all around it, and it
21 affixes it, holds it.

22 Q. I got you.

23 A. So now you have a coating of the fixation
24 product around the Prolene fiber. All right. Now,
25 that was formed when they took the explant from the

1 human body and put it in formaldehyde. They do that
2 to preserve it.

3 Q. Right.

4 A. They also do it to fix it so that if some
5 pathologist wants to slice a piece of it, it's rigid
6 enough that it can be sliced and given a decent
7 microtome sample.

8 Now, if somebody said, "Well, I want to
9 remove that material," well, go back to basic
10 chemistry, the chemical reaction here, and say,
11 "Well, since this is an equilibrium reaction, if I
12 add water to it and put the water into the
13 cross-linked material" -- in our case, we added
14 heat. We used 70 degrees. Now, why did we add
15 heat? Because heat increases the rate of the
16 chemical reaction, and I didn't want to sit around
17 for a month waiting for this reaction to take place.

18 Q. Fair enough.

19 A. So we put that in water, and we heated it.
20 And see what happens? It reverses.

21 Q. All right. So let me stop you there.

22 A. All right.

23 Q. So to break this bond, all I've got to do
24 is stick the explant in water. And if I don't want
25 to wait around a month, I heat it up a little bit?

1 A. Well, use the protocol that we have
2 described in here, yes, sir. But that's
3 basically -- generally speaking, that's correct.

4 Q. And this is where I'm kind of -- this is
5 where I -- you know --

6 A. It's too simple, isn't it?

7 Q. That's kind of my question. So,
8 basically, my guys are so dumb they don't know to
9 just stick it in water. That's what you're saying?

10 MR. HUTCHINSON: Object to form.

11 BY MR. MONSOUR:

12 Q. I mean, that's pretty much what you're
13 saying, right?

14 MR. HUTCHINSON: No. Object to form.

15 He's not answering that, Counsel.

16 THE WITNESS: No, sir, I'm not saying
17 that. I'm just saying this is what I do.
18 This is the chemistry that I use. It's very
19 well stated. It's 66 years old. And some
20 other folks are missing that, and I don't
21 know why. That's their issue. But I'm
22 explaining what I've done, and what I've done
23 is good science.

24 BY MR. MONSOUR:

25 Q. Let me do this. I'm going to ask my

1 question in a more gentlemanly manner, because my
2 experts might end up reading this deposition. So
3 I'll ask it in this way. I won't use the word
4 "dumb."

5 If my experts had just known to stick
6 these explants in water, they could have gotten off
7 this cross-linked protein-formaldehyde polymer that
8 formed on the outside of the explants and could have
9 just looked at the pristine stuff?

10 MR. HUTCHINSON: Object to form. It
11 also calls for speculation.

12 BY MR. MONSOUR:

13 Q. Right?

14 A. It's a little bit more -- not complicated,
15 but there's a little bit more to it than just
16 sticking it in water.

17 You have to put it in water. You need to
18 heat it up. You have to be careful with the
19 explant. But, basically, this chemical reaction
20 will clean the explants.

21 Q. All right. Now, as I look at your -- as I
22 look at your -- I think it was your cleaning
23 protocol, the one that had all the colors on it, --

24 A. Yes, sir.

25 Q. -- you mentioned using bleach.

1 A. Yes, sir.

2 Q. Why do you use bleach?

3 A. Well, because when you reverse this
4 reaction, you undo the cross-linked material, and
5 you still have flesh.

6 Q. Okay.

7 A. A quick, easy, mild way of getting rid of
8 that is to use a little bleach, and then it's gone.

9 Q. So let me see if I understand this. The
10 water breaks the bonds. The bleach has a way of
11 removing the broken-down remnants of what the bonds
12 had formed?

13 A. Correct, the flesh.

14 Q. The flesh.

15 A. Uh-huh (affirmative response).

16 Q. But then there's also formaldehyde that's
17 there too, and it gets rid of that as well?

18 A. Yes, sir.

19 Q. So, literally, if I want to clean these
20 things, if I do water and bleach and do those well,
21 can I clean these perfectly?

22 MR. HUTCHINSON: Object to form.

23 THE WITNESS: When you say "perfectly,"

24 I'm not sure that you will ever get

25 1,000 percent of all the proteins off, but

1 you'll have a very fine, pristine type
2 material that you can examine.

3 BY MR. MONSOUR:

4 Q. Okay. So let me ask this question. And
5 this is, again, one, two, three, four. Okay.
6 You're talking to four (indicating himself).

7 Why when you say, I don't know that you
8 could ever get all the protein off, if all you
9 really need is some water to break it down and some
10 bleach to get what's broken down away, why couldn't
11 you get it all off?

12 A. Well, we found -- and you'll see as we
13 look through these scanning electron micrographs
14 that we've taken after -- even our -- not five
15 steps, we'll see that if we look at some of our
16 scanning electron micrographs, that after these five
17 major steps of cleaning that we've done, there's
18 still a little speck that you can see where there's
19 remnants of protein that's still on the explant.

20 So when I talk about simply putting in --
21 if I have enough time that I can wait and put this
22 in water, give some heat to it, it will clean the
23 explants efficiently as any process as you can find.
24 It's all in the chemistry right here.

25 Q. Okay.

1 A. This equation defines what can be done and
2 what we did.

3 Q. Okay. Let me ask this: Do you believe
4 that when it's implanted in the body, the Prolene is
5 implanted in the body, that it can undergo oxidative
6 degradation?

7 A. No, sir.

8 Q. And you're unequivocal about that? The
9 Prolene, when it's implanted, does not degrade when
10 it's put in the body, in your opinion, true?

11 A. That's true, sir.

12 Q. What would you need to see, what evidence
13 would you need to see as a scientist to convince you
14 that it did undergo degradation in the body?

15 A. There would need to be a carbonyl index or
16 carbonyl bonds formed. There would need to be a
17 significant reduction in molecular weight. There
18 would need to be a significant reduction in physical
19 properties, such as tensile strength and elongation.

20 And if you do not have those
21 characteristics occurring as a result of
22 implantation, then the product did not degrade, the
23 product being Prolene.

24 Q. So what are some tests that you could do
25 to test whether or not an explanted piece of Prolene

1 has degraded? In other words, you've mentioned
2 carbonyl bonds, molecular weight, physical
3 properties, tensile, all those kind of things.

4 A. (Witness nods head affirmatively.)

5 Q. What are some tests you could do to look
6 at explanted Prolene to see if it was degraded?

7 A. Well, you would run the tests that I've
8 just mentioned.

9 Q. Okay.

10 A. You would perform the activities, the
11 scientific activities that I just mentioned to you,
12 i.e., you would use a Fourier transform infrared
13 spectrometer, FTIR, and you would get a fingerprint
14 of the chemical composition of the surface of the
15 explanted material. And if there was -- if there
16 was hydrolytic bond breakage, as would occur -- or
17 let's just stay bond breakage that would occur under
18 the circumstances that you've asked, what I would
19 need to show, it would show whether there were any
20 bond breakages or not with strong carbonyl
21 absorption.

22 Then, in addition to that, you would have
23 explants that would have lost its physical strength.
24 Its elongation would be less. Its tensile strength
25 would be less. Its compliance would be less. So

1 those are the characteristics. Now, they all have
2 to follow each other.

3 Q. Okay.

4 A. So molecular weight would be less.

5 Q. So it's talk about FTIR.

6 A. Okay.

7 Q. To show degraded polypropylene or oxidized
8 polypropylene, where do you have to have a reading
9 for on FTIR?

10 A. You'll get a carbonyl reading somewhere in
11 the range of 1750 to 1730 in general. That's
12 reciprocal centimeters.

13 Q. So if we look at an FTIR report and it
14 shows a reading between 1730 and 1750, is that
15 evidence of oxidated polypropylene?

16 A. Well, not necessarily in this case. It
17 would say what you need to do is look a little
18 farther at some of the other tests that we've talked
19 about.

20 Because in Prolene you have two materials
21 that also have carbonyl bonds, and that's calcium
22 stearate and dilauryl thiodipropionate, DLTPD, which
23 is an antioxidant.

24 Q. So the first one is called calcium what?

25 A. Stearate, S-T-E-A-R-A-T-E, --

1 Q. Okay.

2 A. -- and then your antioxidant, DLTDP, those
3 both. So you've got to be careful. You may be
4 seeing one of those.

5 Q. All right.

6 A. So what we would then need to do is say,
7 "Okay. What about molecular weight? What happened
8 to molecular weight? And then, after that, what
9 happened to our physical properties? We need to do
10 tensile and elongation and do that curve and see
11 whether or not the toughness has been diminished."

12 Q. Okay. Hold on. So we're going to go
13 through these one at a time. You moved quick. All
14 right.

15 So the first thing we're going to look at,
16 if we've got an FTIR and it has a positive reading
17 at, let's say, 1742, in your mind, you're saying
18 that could be oxidated or degraded polypropylene.
19 Let's do some further tests, correct?

20 A. I think that's correct.

21 Q. And so the next thing you would do is you
22 would test it for calcium stearate and DLTDP?

23 A. Well, because they have carbonyl groups
24 and could show up in that range, that's why I would
25 say let's do something else to rule them out as the

1 reason for the carbonyl group.

2 Q. Okay.

3 A. All right. Then you run molecular weight.
4 And if there is degradation, there will be a decline
5 in molecular weight. And after you've run molecular
6 weight, you say, okay, that suggests to me we've got
7 a problem here. We've got oxidation. Let's do our
8 physical property tests to make sure that
9 absolutely, 1,000 percent sure that we've got
10 degradation.

11 Q. So let's look at some of these, and let's
12 talk about them.

13 How do I test -- so we've done our FTIR.
14 Let's say I've got a positive reading at 1742. So I
15 go to step two. I look at calcium stearate. How do
16 I look at that?

17 A. Well, in the spectra, if we get a spectra
18 and there's a carbonyl group in the range we talked
19 about, that may be calcium stearate. And we can't
20 really tell 1,000 percent if that's calcium
21 stearate, if it's DLTDP, or if it's a C=O formed
22 from a ketone from the oxidation of Prolene. But we
23 know there's a carbonyl group. We just don't know
24 which of those three it might have come from.

25 Q. Can I determine which one of those three

1 it might have come from? Are we able to do that?

2 A. Not just from an infrared spectra. That's
3 why you need the additional tests that I'm talking
4 to you about.

5 Q. So what you're saying is --

6 A. Very indicative that there's an issue here
7 that could suggest we've got oxidation, but we've
8 got to refine these tests to make absolutely certain
9 that there is oxidation.

10 Q. And, at that point in time, that's when
11 you go look at molecular weight and physical
12 properties?

13 A. Yes, sir.

14 Q. Okay. I think I got it. So you get a
15 positive reading at 1742 on the FTIR, and at that
16 point in time you know it could be one of three
17 things: Oxidated polypropylene, calcium stearate,
18 or DLTDP, correct?

19 A. Yes.

20 Q. Now, you can't really tell which one it is
21 because it's only showing positive for a carbonyl
22 group; therefore, you go to a second round of tests,
23 which would include molecular weight and physical
24 properties, correct?

25 MR. HUTCHINSON: Object to form.

1 THE WITNESS: Yes.

2 BY MR. MONSOUR:

3 Q. Molecular weight, how do we measure that,
4 and how significant does the molecular weight drop
5 have to be for you to think it's significant?

6 A. You measure molecular weight by gel
7 permeation chromatography, GPC as it's talked about,
8 or it's also referred to as size exclusion
9 chromatography. And that allows you to determine if
10 there's been a significant decrease in molecular
11 weight.

12 You will get a number-average molecular
13 weight, you'll get a weight-average molecular
14 weight. And the weight-average molecular weight and
15 the Z-average molecular weight will tell you the
16 higher molecular weight components.

17 If they've been -- if we've had a
18 significant reduction in molecular weight, that
19 affected the higher molecular weight components. If
20 there is a significant reduction in molecular
21 weight, you say, okay, we may have another issue
22 here. Let's check it and make absolutely sure.
23 Let's do physical property tests.

24 Q. So question, you just used the term "a
25 significant drop in molecular weight." I'm not a

1 polymer guy. What would be a significant drop in
2 molecular weight?

3 A. I would say 20 to 30 percent, maybe more.
4 I would have to look at the numbers to see. Let's
5 restate that. Let's use 30 percent as a significant
6 drop.

7 If it's going to oxidize, it will give us
8 that kind of reduction. There is some error in
9 molecular weight determination, so we have to keep
10 that in mind.

11 Q. And what is the error in molecular weight
12 determination?

13 A. It depends on who does it, and it would be
14 in the range of around 10 percent. So we have to --

15 Q. Are you saying the margin of error for
16 molecular weight measurements is about 10 percent?

17 A. It can go as high as 10 percent, yes, sir.

18 Q. So one of the issues that we have with
19 molecular weight measurements is if the margin of
20 error is 10 percent either way, that could get you
21 fairly close to your 30 percent that you're talking
22 about, right?

23 A. I'm not sure. I don't understand.

24 Q. Sure. If the margin of error is 10
25 percent -- is it 10 percent total or 10 percent

1 either up or down?

2 A. Well, you could be estimating them. Let's
3 say you had 330,000. 10 percent is 33,000. If you
4 take that off, you're down around 30,000, so
5 whatever that number would be. So it's plus or
6 minus that number.

7 Q. Okay. Good. But that range, a 10 percent
8 range in one direction combined is about a
9 20 percent swing from top to bottom. That's, I
10 guess, what I'm getting at.

11 What you're telling me is once you get to
12 about 30 percent, that's when you can really say
13 that there's probably been a molecular weight loss.
14 And I guess my point is 20 is not that far from 30.
15 That's why you're going to the next test, which is
16 physical properties and toughness, right?

17 MR. HUTCHINSON: Object to form.

18 THE WITNESS: That is correct.

19 BY MR. MONSOUR:

20 Q. Okay.

21 A. You want to make certain.

22 MR. HUTCHINSON: Doug, after you go
23 through physical properties, can we take a
24 little break?

25 MR. MONSOUR: Yeah, absolutely.

1 THE WITNESS: And one of the things I
2 want to emphasize is all of these things have
3 to happen.

4 BY MR. MONSOUR:

5 Q. You've got to do them all?

6 A. All have to happen.

7 Q. If I were to do just FTIR testing and say,
8 ah-ha, you would say, I'm doing bad science?

9 A. You're doing incomplete science.

10 Q. Incomplete science. Okay.

11 So the physical property testing would
12 include -- you would look at tensile strength?

13 A. Yes, sir.

14 Q. Elongation?

15 A. Yes, sir.

16 Q. What else?

17 A. That will give you a value for toughness.
18 If you plot tensile strength and elongation, that
19 will give you a value of toughness, and you do that
20 against a control. Of course, you always have to
21 use a control that hadn't been subjected to any of
22 the tests that we're saying we're performing here.

23 Q. Okay.

24 A. No control, your data is of no
25 significance.

1 Q. So I'm going to write over here on the
2 left-hand side "must have a control." Okay?

3 A. (Witness nods head affirmatively.)

4 Q. Is that a fair statement?

5 A. Yes, sir, it is.

6 Q. So how do you measure tensile strength,
7 and how do you measure elongation?

8 A. Well, you use a machine called an MTS, a
9 material testing system. There's an ASTM test for
10 this. It requires at least five samples, five
11 duplicate samples. In the case we're talking about,
12 you would take fibers, Prolene fibers. You would
13 clamp them into two clamps.

14 And this machine that we're talking about
15 has the ability then -- we program it to move those
16 clamps apart at a certain rate. You do that, and it
17 stretches it and stretches it. And then it plots it
18 on the recorder over here the amount of force that's
19 being applied. And you're also looking at, well,
20 how long had it -- from the original sample length
21 of, say, like one inch, it goes two inches when it
22 finally broke. That's 100 percent elongation. You
23 can determine that.

24 So you're getting elongation and the
25 strength required to break the fiber. When the

1 fiber is broken, that's its ultimate tensile
2 strength. And that's also its ultimate elongation.

3 You plot that data, and that's how -- and
4 the area under the curve, as I've shown you here in
5 this report that I've written, is toughness.

6 Q. Okay.

7 A. And then you compare that to the control,
8 the data that you've achieved.

9 Q. So give me -- tell me what you just told
10 me and use fishing line as an example.

11 A. Well, you could put fishing line between
12 the two clamps. You could put textiles between the
13 two clamps. You could put leather between the two
14 clamps. You can actually put concrete between the
15 two clamps.

16 Q. And the heavier gauge fishing line would
17 have different tensile strengths as the lower weight
18 fishing line, correct?

19 MR. HUTCHINSON: Object to form.

20 THE WITNESS: You're talking about the
21 smaller braided line?

22 BY MR. MONSOUR:

23 Q. Yeah.

24 A. Because you measure it on area, yes, sir.

25 Q. Does that testing that you're talking

1 about, does that test both tensile and elongation?

2 A. Yes, sir.

3 Q. And do you test it all the way up until it
4 snaps?

5 A. Yes, sir.

6 Q. And what's the snapping point called?

7 A. The ultimate tensile strength or the
8 ultimate elongation. That's the snapping point, and
9 finally it breaks.

10 Q. And what's it called again?

11 A. Ultimate tensile strength.

12 Q. Okay.

13 MS. KROTTINGER: Can we take a break?

14 Technical difficulties.

15 MR. MONSOUR: We are going to take a
16 break.

17 (A BREAK WAS TAKEN.)

18 BY MR. MONSOUR:

19 Q. We've taken a short break, Dr. Thames.
20 Are you ready to continue?

21 A. Yes, sir.

22 Q. We were kind of talking about some of the
23 process that you would go through after you would
24 get an FTIR reading that was positive for -- or
25 potentially positive for degraded polypropylene,

1 correct?

2 A. Yes, sir.

3 Q. And we had gotten down, and we had talked
4 about how you had first tested and that it came in
5 that range of 1730 to 1750. That would start your
6 inquiry, and you would then follow up with molecular
7 weight and physical properties and those kind of
8 things, correct?

9 A. Yes, sir.

10 Q. Now, you said that you thought a
11 30 percent drop in molecular weight would be kind of
12 where you would -- that's where you would determine
13 something was significant?

14 A. Well, first of all, you've got to take
15 into consideration the -- who's running the test and
16 what kind of error we think. Beyond that, if we've
17 got anywhere from a 20 to 30 percent reduction in
18 molecular weight, I would be concerned, and then we
19 would go to the next test.

20 Q. Okay. Now, where did you -- you know, one
21 of the things we do when we've got litigation -- and
22 you know this because you prepared your report. We
23 ask a question. We say, "What's your opinion?" And
24 then we try to find out is there anybody else that
25 agrees with you.

1 So when you're talking about a 20 to
2 30 percent drop in molecular weight, is there an
3 authority that you would rely upon for that drop as
4 being significant?

5 A. I haven't pursued that, no, sir.

6 Q. So would it be fair to say that the 20 to
7 30 percent drop in molecular weight would be the
8 Shelby Thames' criteria, and you are not certain if
9 there is any support in the literature for that?

10 MR. HUTCHINSON: Object to form.

11 THE WITNESS: I haven't really looked
12 for it. But what I also want to be sure we
13 include is that all of the steps that I've
14 talked to you about have to be performed in
15 order to come to a final conclusion.

16 BY MR. MONSOUR:

17 Q. Right, right. But I was just asking about
18 that one specific area, the molecular weight.

19 A. Yes, sir.

20 Q. There might be a bible on this stuff that
21 I don't even know the name of. So if there is a --
22 you might say, "Yeah, it's in Bill's Bible of
23 Polymer Chemistry, you dummy." I don't know that
24 that book exists.

25 So my question would be, is there any

1 authority that you would cite for that being the
2 drop?

3 A. I think I've answered that.

4 Q. Okay. Now, as far as your -- you
5 mentioned when you were going to do the physical
6 properties test you would follow the ASTM
7 guidelines?

8 A. Yes, sir.

9 Q. Why would you follow ASTM guidelines?

10 A. Because those are guidelines that have
11 been set by people in the profession to say, well,
12 we've got to consider these approaches and do it
13 this way. Otherwise, the data we get may not be
14 reliable.

15 For instance, they require five specimens
16 be run and take the average of that. When you're
17 running a test, like an MTS test, tensile strength
18 and elongation, in the process of putting the
19 material in the clamps and clamping them down,
20 number one, you could not have your clamps set just
21 right. And so the number you got there -- the clamp
22 could slip, and so the elongation would be greater
23 than it actually is.

24 So you want to make certain that you have
25 enough samples replicated that if those things occur

1 and you have one that is completely off the charts,
2 you throw that out and say that's an outlier. That
3 data is not really true. So that's why you run five
4 samples and make sure that the number you are seeing
5 is a significant number.

6 Q. If there are not five samples run, would
7 you place much credibility into the results?

8 A. I would give -- the credibility I would
9 give to it would determine how many samples were
10 run. The fewer the number of samples, then the more
11 questionable that becomes.

12 Q. Okay. You've used the word "toughness"?

13 A. Yes, sir.

14 Q. What does "toughness" mean?

15 A. Well, I often use a downhome example of
16 toughness. You may not remember this because you
17 may not be old enough. But there used to be a
18 gentleman by the name of John Cameron Swayze who was
19 on TV, and he advertised Timex watches. He would do
20 some awful things to a Timex watch. He would put
21 them on a propeller of an outboard motor and crank
22 the thing and show it on TV. And he said, "It takes
23 a licking and keeps on ticking."

24 Q. I actually do remember that, I think.

25 A. That's tough.

1 Q. So toughness is kind of what it sounds?

2 A. Yes, sir.

3 Q. So it's the ability to, I guess, be hit or
4 be challenged in some way physically and not fall
5 apart?

6 A. And still perform.

7 Q. And still perform. Okay.

8 You said to get to toughness you use the
9 tensile and elongation measurements?

10 A. Yes, sir. You plot those. It's like I've
11 shown in my report here.

12 Q. Now, one of the theories that has been
13 proposed is that your cleaning procedure might be a
14 little too much.

15 Have you ever heard that?

16 MR. HUTCHINSON: Object to form.

17 THE WITNESS: I don't believe in this
18 cleaning procedure I've heard that, but, you
19 know.

20 BY MR. MONSOUR:

21 Q. Well, let me ask you this: Is it possible
22 in your cleaning procedure that you've done that
23 there is oxidized polypropylene on the surface of
24 the explants, and because your polypropylene --
25 because your cleaning procedure is so thorough, you

1 actually clean the layer of degraded polypropylene
2 off the surface?

3 A. I don't believe that happened, sir.
4 That's why we used this very mild set of
5 circumstances.

6 Q. Okay.

7 A. I mean, when we put this in water, then
8 the reaction reverses. And then we used sodium
9 hypochlorite to take care of the flesh, to move it
10 out of the way. That's an oxidizing environment.
11 So we're not going to remove something that's
12 oxidized with an oxidizing environment.

13 Q. Okay.

14 A. So this is a very mild set of
15 circumstances. I don't believe that's true.

16 Q. Your cleaning procedure actually involves
17 a few more things than just water, heat and
18 bleach, --

19 A. Yes.

20 Q. -- in all fairness, doesn't it?

21 A. Yes, sir. We use protein to -- which in
22 the event there's still clean protein, it will help
23 remove some of it. It's an enzyme called
24 Proteinase K, P-R-O-T-E-I-N-A-S-E-K, I believe.

25 Q. So you used some Proteinase K?

1 A. Yes, sir. It's an enzyme.

2 Q. And what does that do?

3 A. Well, it helps open the proteins and the
4 flesh more so that if there's any carbonyl groups
5 that are there that haven't been removed, they're
6 taken away. It's just another cleaning process
7 basically, a little bit more rigorous. But it's an
8 enzyme. It's a mild enzyme, but it works a
9 different way.

10 Q. Is there any way that you can guarantee
11 that you're not cleaning off a layer of oxidized
12 polypropylene? Can you be 100 percent sure that
13 you're not doing that?

14 A. I feel I'm 100 percent sure I'm not doing
15 it because I'm using these mild conditions.

16 In the article that we talked about here
17 with Guidoin, he talks about strong chemicals.
18 We're not using strong chemicals. To me, this is as
19 mild a set of circumstances that you could get to
20 clean these explants.

21 We're using the reversal of a basic
22 chemistry that formed the casing or the fixation
23 process. We're just reversing that.

24 Q. Don't you use some steps in your protocol
25 that have some like vibration or something in there?

1 A. Sure.

2 Q. What's that?

3 A. That's in case you've got a piece of loose
4 material that doesn't come off, you help that by
5 vibrating it.

6 Q. So, basically, you're cleaning -- and some
7 of your cleaning steps kind of involve repetition.
8 You kind of do things more than once, right?

9 A. That's correct.

10 Q. So your cleaning steps involve water,
11 bleach --

12 A. Well, let's look at the --

13 Q. Here it is right here.

14 MS. KROTTINGER: It's on page 100.

15 BY MR. MONSOUR:

16 Q. Oh, there was another question that I was
17 going to ask you. I do want to clear this up before
18 we go further so that we're not confused.

19 I got from Mr. Hutchinson new cleaning
20 steps two days ago that are different than -- I
21 don't know whether they're different from this or
22 they're different from the original report.

23 MR. HUTCHINSON: Why don't you ask him
24 why he amended -- he served amended
25 case-specific reports?

1 BY MR. MONSOUR:

2 Q. Would you tell me why two days ago we got
3 amended case-specific reports with different
4 cleaning steps?

5 A. Because one of the protocols that we have
6 used was inadvertently placed in the case-specific
7 reports. And in those cases, we were using longer
8 hours to clean the explant. And in the
9 case-specific reports, as you know, we have a lot of
10 explants to clean. They're coming in on a regular
11 basis. We needed to find a way to do it in a
12 shorter period of time.

13 So we reduced the period of time from the
14 original cleaning explant. So the ones in the
15 case-specific report were being cleaned in shorter
16 periods of time, but the process was the same.

17 Q. So you served 20 case-specific reports.
18 In each of those case-specific reports, the first 20
19 that you served, the cleaning protocol that you had
20 in there was a protocol that was actually not
21 followed. Is that true?

22 A. That's correct.

23 Q. And then two days ago, you amended and
24 realized, oh, shoot, I gave them the wrong one. I
25 actually used this second one, correct?

1 A. Yes, sir.

2 Q. Is the second one that you amended in each
3 of the 20 reports identical to what is on page 100
4 of your report?

5 A. No. This is not the amended one.

6 Q. So 100 is not the amended one. 100 is the
7 incorrect one?

8 A. Well, it's a different one. I wouldn't
9 call it incorrect. It's a different one. It's the
10 same steps, but they're at different -- for
11 different time periods basically.

12 Q. But it is the incorrect one?

13 A. It's in the wrong place.

14 Q. Which would make it incorrect.

15 MR. HUTCHINSON: I think it's outdated.

16 It's outdated protocol.

17 MR. MONSOUR: Time-out.

18 (OFF-THE-RECORD DISCUSSION.)

19 MR. MONSOUR: So let's go back on the
20 record. You ready?

21 THE WITNESS: Yes, sir.

22 BY MR. MONSOUR:

23 Q. So one of the questions that I have is, if
24 I'm looking at your protocol on page 100, that is
25 not the protocol that you followed with the explants

1 that you did, correct?

2 A. Yes, sir.

3 Q. You changed them, as you're saying, to
4 shorten the time because you had a lot more to do?

5 A. Yes, sir.

6 Q. Were you still able to achieve good
7 results with the shortened time frames?

8 A. Yes, sir.

9 MR. MONSOUR: Do we have one that's the
10 newer ones -- actually, hold on. I bet I do
11 right here. I think this is an amended one.
12 Okay. I've got it right here.

13 BY MR. MONSOUR:

14 Q. So how did you catch the error that the
15 wrong one -- that the wrong cleaning protocol was
16 included in the general and the case-specific
17 reports?

18 MR. HUTCHINSON: Object to form.

19 THE WITNESS: In looking at the cleaning
20 protocol, I noticed that this was 42 hours
21 rather than the short -- with the original
22 cleaning schedule. You'll see on the third
23 step of the original that it says 70 degrees
24 Centigrade for 42 hours and then spray rinse.

25 I noticed that this was 42 hours, and it

1 should have been about half that. And then I
2 went back and looked and found out that we had
3 put the wrong cleaning schedule in the
4 case-specific reports.

5 BY MR. MONSOUR:

6 Q. So, in all fairness, you got the wrong
7 cleaning schedule in 21 different reports?

8 A. That's correct, initially.

9 Q. But it is accurate?

10 A. That is correct.

11 Q. Are you sure it's accurate now?

12 A. Yes, sir.

13 Q. So let's go through -- well, let me ask
14 you. Should we go through the wrong procedure, or
15 should we go through the right procedure?

16 MR. HUTCHINSON: Object to form. For
17 the objection, it's not the wrong procedure.
18 It's an outdated procedure, Counsel.

19 THE WITNESS: That was the point I was
20 trying to make. The procedure is not wrong.
21 It's outdated. It wasn't the one we used.
22 Now, the procedure we used is the shorter
23 one, the shorter time frame. So we probably
24 should use that because that's in 21
25 case-specific reports.

1 BY MR. MONSOUR:

2 Q. So let's use the one that you actually
3 used. Let's use that one.

4 MR. MONSOUR: Do you have a clean copy
5 of one of those?

6 MS. KROTTINGER: I do.

7 MR. HUTCHINSON: Of the case-specific
8 report?

9 MS. KROTTINGER: We'll just use Justus.

10 MR. MONSOUR: I just want to look at --

11 MR. HUTCHINSON: Not with me, but I'll
12 go get one.

13 MR. MONSOUR: Here, this is from Justus.

14 BY MR. MONSOUR:

15 Q. So I'm going to hand you your amended
16 case-specific report from Justus, J-U-S-T-U-S.

17 MR. MONSOUR: We'll mark it as
18 Exhibit 5.

19 (EXHIBIT NO. 5 MARKED.)

20 BY MR. MONSOUR:

21 Q. And this is not -- I'm using this as an
22 exemplar, not as my case-specific depo for Justus.
23 But this is just the one that I have handy. We'll
24 talk about the Justus case specifically in the
25 Justus case deposition. Okay?

1 A. Yes, sir.

2 Q. So if we look at this, if we look at the
3 steps that were taken, can you kind of walk us
4 through -- well, first off, in Exhibit 5 in front of
5 you is a cleaning protocol, correct?

6 A. Correct.

7 Q. That is the correct cleaning protocol that
8 you actually used to clean the 20 different explants
9 that you cleaned and looked at for case-specific
10 reports, correct?

11 A. That's correct, sir.

12 Q. This protocol that is set up here, where
13 did you get this protocol from?

14 A. I devised the protocol in discussing this
15 issue with Dr. David Ong -- Kevin Ong -- excuse
16 me -- from Exponent. And I need to make it clear
17 that he is actually the one that did the cleaning of
18 the materials.

19 Q. Okay.

20 A. I put it together in discussion with him
21 based on the chemistry that we talked about, the
22 reversible reaction and the mildness of that, and
23 that's how this was brought about.

24 Q. So a couple of questions. I want to go
25 through this. I'm not an expert in cleaning things,

1 as we've discussed.

2 As far as the protocol, you came up with
3 it with Kevin Ong?

4 A. Yes, sir.

5 Q. Was it more you coming up with it or more
6 Mr. Ong coming up with it?

7 A. More my coming up with it. "This is what
8 I would like for you to do. Are you okay with that?
9 Do you have any reason to believe this is not what
10 we should be doing?", those kind of questions.

11 Q. I don't know who Kevin Ong is.

12 A. He has a Ph.D. in biomaterials, and he
13 works for the Exponent company.

14 Q. What is Exponent?

15 A. It's a commercial laboratory providing
16 scientific services to the scientific community.
17 It's very broad.

18 Q. Did you select Exponent?

19 A. No.

20 Q. Did Ethicon select Exponent?

21 A. I'm not sure. My attorneys were involved
22 with Exponent. I'm not sure who selected it.

23 Q. Had you ever worked with Exponent before?

24 A. Yes.

25 Q. In what capacity?

1 A. I just went to their labs a couple of
2 times on other cases where I would pick up samples
3 or see what they had done, nothing to do with this
4 case.

5 Q. In litigation matters you've worked with
6 them?

7 A. Yes, sir.

8 Q. Where are they located?

9 A. I don't know. Philadelphia is one place.
10 But they're out in California, and they've got other
11 places, which I don't know the details of.

12 Q. As far as the protocol, when I first asked
13 you where it came from, you came up and actually
14 pointed at your head. Is there any -- is this
15 protocol, this cleaning protocol for explanted
16 implants, is this protocol published anywhere or
17 peer reviewed anywhere?

18 A. Not to my knowledge at this point.

19 Q. Have you ever seen this specific protocol
20 used before?

21 A. Not to my knowledge.

22 Q. Is this protocol -- are you familiar with
23 the ISO standard for cleaning explants?

24 A. It's my understanding there isn't really a
25 specific ISO standard for cleaning explants, but I

1 didn't really look.

2 I understand the chemistry of the
3 formation of the proteins around the fibers, and I
4 wanted to devise a technique that was as mild as
5 possible, and I've done that, and that's what we've
6 used to clean these explants with.

7 The other thing that is important that you
8 haven't gotten to yet, but I need to say it at this
9 time, is after each of these steps, after each of
10 the cleaning steps, the explants were sent from
11 Dr. Ong back to my laboratories where we performed
12 FTIR, scanning electron microscopy and light
13 microscopy on them at each step so we could see the
14 progress of cleaning. And that information is
15 included, of course, in each of these case-specific
16 reports.

17 So what we were doing, we were following
18 them. We basically could see with our
19 instrumentation if that process was being effective
20 or not.

21 Q. So what you're saying is -- and Dr. Ong is
22 O-N-G?

23 A. Yes, sir.

24 Q. Dr. Ong is -- where is he located?
25 Philadelphia?

1 A. That's right.

2 Q. So he would do one of these steps and then
3 ship the implants back to Mississippi, and you would
4 do the FTIR and light microscopy, send them back to
5 him, and he would do another step and send it back
6 to you, and you would do more FTIR, light
7 microscopy, and send them back the whole way
8 through?

9 A. That's correct.

10 Q. So give me an example. How long did the
11 whole process take? Like when you got an explant,
12 from the time you got it until you completed the
13 steps, is it a few-week process?

14 A. I can't really tell you. I would have to
15 go through here and look at the time frame that they
16 kept the explant and then add a couple of days for
17 transmitting them back and forth. Whatever that
18 works out would be the time.

19 Q. Y'all just overnight them back and forth?

20 A. Absolutely.

21 Q. Okay. Now, a couple of the steps I wanted
22 to ask you about.

23 A. Sure.

24 Q. Did you use a control; in other words, did
25 you send a control through this process?

1 A. Absolutely. You must have a control.

2 Q. You know how I know that?

3 A. I said it before.

4 Q. Because you told me. See, I wrote it
5 right there, "Must have a control." I'm a good
6 student.

7 A. Yes, sir. I like that.

8 Q. Must have a control.

9 A. You'll pass my test when this is over
10 with.

11 Q. I tell you what, I think I might. I
12 might.

13 So as we look through here, some of the
14 things that are happening are we go through the
15 first step, distilled water, correct?

16 A. Yes, sir.

17 Q. For one hour?

18 A. No, sir, 30 hours. It's 70 degrees -- oh,
19 you're talking about step one?

20 Q. Yeah, I said first step. I'm sorry.

21 A. No, it was my mistake. They soaked it in
22 distilled water for one hour, yes, sir.

23 Q. And then it goes -- the second step is
24 ambient overnight drying followed by SEM.

25 A. They performed an SEM. It's in their

1 records, and those documents will be presented by
2 Dr. Ong. He's also presented those to me. You have
3 those, I believe.

4 MS. KROTTINGER: Uh-huh (affirmative
5 response).

6 MR. MONSOUR: Just as an aside, is there
7 a deposition set up for Dr. Ong?

8 MR. HUTCHINSON: No.

9 MR. MONSOUR: Is he a testifying expert
10 or a consulting expert?

11 MR. HUTCHINSON: I don't know which
12 litigation. Are you talking about the
13 Wave 1?

14 MR. MONSOUR: Yeah.

15 MR. HUTCHINSON: He is a consulting
16 expert, I think. He's not -- I'll tell you
17 this, he's not a testifying expert.

18 MR. MONSOUR: All right.

19 BY MR. MONSOUR:

20 Q. So the second step is ambient overnight
21 drying followed by SEM. What does that mean?

22 A. Ambient drying is drying at room
23 temperature. And then after it dried at room
24 temperature -- you see it had been soaked in water
25 for one hour, dried at room temperature, and then

1 they performed SEM analysis, and then they sent it
2 me.

3 Q. Was the first step primarily to basically
4 just get -- wash off as lightly as you can, let it
5 dry, and then take pictures to kind of know what
6 your starting point is?

7 A. That's exactly right.

8 Q. Your second step, it says distilled water
9 bath 70 degrees Celsius 30 hours.

10 A. That started my chemical reaction we
11 talked about here.

12 Q. And 70 degrees Celsius is what Fahrenheit?

13 A. It's about 130, approximately.

14 Q. So that goes on for 30 hours. That's the
15 start of your chemical reaction that we've talked
16 about quite a bit, correct?

17 A. Yes, sir.

18 Q. And then the next step is what?

19 A. Sodium hypochlorite for 15 minutes.

20 Because if we've gotten some -- we've reversed that
21 reaction some, and we have some now free, unreacted
22 tissue, and we want to get rid of it so that we're
23 closer -- we're working from the outside moving in.

24 Q. Is it kind of like you're taking off
25 layers? Is that a fair way to say it?

1 You put some water in. That breaks down
2 the outer later, and then you take the bleach to get
3 what you broke down, and then you go back in water
4 and it breaks it down a little more. Is that a --

5 A. I think that's a fair way to look at it.

6 Q. All right. So NaOCl, is there another
7 name for that?

8 A. Sodium hypochlorite.

9 Q. Is there another name for it?

10 A. Bleach.

11 Q. There you go. Like Clorox?

12 A. Yes.

13 Q. Do y'all actually use Clorox?

14 A. No. It's stated what we used here.

15 Q. So then the next step is after 15 minutes.

16 The fifth step is what?

17 A. The fifth step is putting it in distilled
18 water and letting it soak a while, one hour, and
19 then you rinse it. That's the rinse where you clean
20 it for one hour in distilled water.

21 Q. Okay. And, basically, when you're doing
22 that rinse, you're trying to get off whatever tissue
23 was probably broken down and removed by the bleach?

24 A. That's correct.

25 Q. Then the sixth step, would you explain

1 that to me?

2 A. That's a drying step. After five, we dry
3 it, and then they take an SEM, and then they send
4 that to me. Then we do our light microscopy, SEM,
5 and we do our work.

6 Now, one thing I want to note here is, you
7 see in blue -- what you'll see when you look at my
8 work is you'll see before cleaning, after cleaning
9 one, after cleaning two, three and four. That's how
10 you'll see that in my report.

11 Q. And that's how you tie it in. So this is
12 that step.

13 So if you take a picture after and it says
14 "after cleaning one," it's after that step that
15 you're talking about?

16 A. That is correct.

17 Q. Now, I do want to ask you this: SEM, what
18 does that mean?

19 A. Scanning electron microscopy.

20 Q. And that would be -- let's use the Justus
21 amended report again. Show me the SEM photos in
22 here. Ah, here it is on page 13.

23 A. Yes, sir.

24 Q. So, as you just explained to us, the first
25 cleaning where you're just kind of rinsing it,

1 you're putting it in a little bit of water to get
2 most of whatever could be on there, you dry it out,
3 and you take SEM. That's picture A in the --

4 A. That's correct.

5 Q. -- top left-hand corner.

6 A. That's correct.

7 Q. It goes through a few more steps. It gets
8 through the sixth step, and then another photo is
9 taken, and that's picture B.

10 A. Well, that's after cleaning one.

11 Q. Right. So that's after the sixth step,
12 which is after cleaning one, which you have marked
13 in blue on your cleaning protocol, correct?

14 A. That's correct.

15 Q. And then it follows all the way down
16 through cleaning five, which is the 25th step, which
17 is the picture that says Justus 1.1 SEM three after
18 cleaning five, correct?

19 A. Yes, sir.

20 Q. Now, I do have a question for you. Some
21 of these say SEM 07, SEM 05, 05, 02, 02, 03. What
22 does the 05, 07, 05 mean?

23 A. We took more SEMs than I could include in
24 this report. That's available for you. We just
25 selected ones that we thought told the best picture

1 to explain what I want to talk to you about as we go
2 through this.

3 Q. And so how many SEMs would you take of
4 each one?

5 A. It varied.

6 Q. But when it says "SEM 5," you just
7 numbered that picture 5?

8 A. Yes, sir.

9 Q. So there's probably a picture 4 I could
10 look at, --

11 A. Sure.

12 Q. -- a picture 6 I could look at for that
13 same level?

14 A. Yes, sir. It would depend.

15 Q. Okay. So hint to somebody getting ready
16 for trial. If they wanted to, they might want to
17 look at those pictures and see what they said,
18 right?

19 A. Yes, sir.

20 MR. MONSOUR: That's my note to all the
21 lawyers that are reading this three months
22 from now. If you want to look at some
23 pictures, they are available. Don't say I
24 didn't tell you.

25 MR. HUTCHINSON: For the record, those

1 have been produced already.

2 MR. MONSOUR: Okay. Good.

3 MR. BOWMAN: Those are the ones produced
4 yesterday?

5 MS. KROTTINGER: Well, two days ago.

6 MR. HUTCHINSON: Two days ago.

7 BY MR. MONSOUR:

8 Q. Let's go back to our cleaning protocol.
9 The seventh step looks like distilled water bath,
10 70 degrees Celsius, 17-and-a-half hours, correct?

11 A. Yes, sir.

12 Q. Why this time did you do it 17-and-a-half
13 hours instead of 30 like you did in the third step?

14 A. Well, number one, we needed to reduce the
15 time because of the number of implants that we were
16 getting in here. So we looked at these and said,
17 well, this is doing a pretty good job. Let's reduce
18 the time.

19 And, obviously, had we gotten through
20 these five steps and they hadn't been clean, we
21 would have to revise and go back and do a longer
22 period of time. But it was giving us what we
23 needed. We were seeing a reduction in the layer,
24 the formation layer around the explant.

25 Q. Fair enough.

1 As in litigation, you had a deadline that
2 you needed to meet. Sometimes you needed to cut a
3 little bit here, but you still wanted to get it done
4 adequately?

5 A. Accurately and adequately, yes, sir.

6 Q. The eighth step, what does it say?

7 A. Hypochlorite in the shaker for one hour.

8 Q. Now, if I look -- if I'm careful at
9 looking at this, it looks like your NaOCl, your
10 bleach, is different than the bleach you used in the
11 fourth step?

12 A. It's the same.

13 Q. So could you tell me why does one say 10
14 to 15 percent NaOCl and the other one says 6 to 14
15 percent NaOCl?

16 A. Let me say this. Dr. Ong did this, and he
17 may have had a different container of sodium
18 hypochlorite, so I may be talking out of -- it may
19 be 6 to 14, but it really doesn't make any
20 difference. It's bleach.

21 Q. And then it says, "shaker one hour"?

22 A. Yes, sir.

23 Q. What's a "shaker"?

24 A. You put the sample in the shaker. And
25 it's just that, it shakes the material back and

1 forth.

2 Q. And so --

3 A. That's to provide physical movement for if
4 there's any hanging-on material that's been --

5 Q. It gets it off?

6 A. Yeah. It may be intertwined, and you're
7 trying to shake that off.

8 Q. So the only thing that's in the shaker is
9 going to be the implant, the bleach, and it goes in
10 there and shakes back and forth for an hour?

11 A. That's correct.

12 Q. Then you take it out, and it says the
13 ninth step is what?

14 A. 6 to 14 percent sodium hypochlorite, and
15 it's in an ultrasonic bath for an hour.

16 Q. What's an "ultrasonic bath"?

17 A. It's a bath that's operated by ultrasonic
18 waves. It's more vigorous than step eight.

19 Q. So how does it do -- how does the
20 ultrasonic bath work? Assume for me the
21 hypothetical that I might not work with ultrasonic
22 baths that often.

23 A. Well, the way that I know to tell you that
24 it works is that it's energy imposed on water such
25 that it has the water waves moving very rapidly.

1 Q. All right. Then the next step is? The
2 tenth step is what?

3 A. That's distilled water again and
4 ultrasonic bath for one hour, but that's just
5 distilled water.

6 Q. Is that basically to rinse the bleach off
7 and any of the other flesh that has broken down?

8 A. Yes, sir.

9 Q. The 11th step is what?

10 A. Desiccation, drying. It's putting it in a
11 desiccator. It's a glass vessel, and they pull a
12 vacuum on it to hurry it up.

13 Q. And they only do that for one hour?

14 A. Yes, sir.

15 Q. And then you again look at it by SEM?

16 A. Yes, sir. And that's my after cleaning
17 two.

18 Q. The 12th step is what?

19 A. They look at by SEM and send it to me.

20 Q. They send it to you after cleaning two.

21 And after cleaning two, you again will
22 perform FTIR and light microscopy?

23 A. And SEM.

24 Q. But doesn't -- does Ong do the SEM, or
25 you're doing the SEM?

1 A. He does it, and we do it.

2 Q. Okay. So y'all both do it.

3 Why is Ong doing SEM if you're doing it?

4 A. I think he wants to see the progression so
5 he can tell how the cleaning process is moving
6 along, and he wants to see that himself, which I
7 understand.

8 Q. Is that a way for him to check that the
9 cleaning is doing what it's supposed to be doing?

10 A. Yes, sir.

11 Q. So then y'all look at it. You do the SEM,
12 the FTIR, the light microscopy following the 11th
13 step.

14 You go to the 12th step, which is?

15 A. Distilled water bath, 70 degrees for
16 18 hours.

17 Q. So it's about the same as the seventh
18 step, except it's half an hour longer, correct?

19 A. Yes, sir.

20 Q. And then you follow that up with the 13th
21 step, which is?

22 A. Again, sodium hypochlorite in the shaker
23 for four hours and then ultrasonic for two.

24 Q. Okay. So it's almost a combination of
25 steps eight and nine?

1 A. Correct.

2 Q. And is there a reason why the 13th step
3 basically listed as one and then eight and nine are
4 listed as two?

5 A. I'm not sure I understand.

6 Q. Well, the 13th step has a shaker and
7 ultrasonic bath.

8 A. Yes, sir.

9 Q. The eighth step is a shaker, and then the
10 ninth step is an ultrasonic bath.

11 So you have it broken down there, and then
12 on one of them you have it combined. I was
13 wondering if there's any significance to that?

14 A. No, sir.

15 Q. The 14th step is what?

16 A. Distilled water rinse, and it's in an
17 ultrasonic bath for one hour, and it's rinsed again.
18 So they took the material out of the 13th step, put
19 it in clean water, clean distilled water, and shook
20 it again for one hour in the ultrasonic bath.

21 Q. Basically to get all the bleach and all
22 the stuff that the bleach took off --

23 A. Yes, sir.

24 Q. -- off the implant?

25 A. Yes, sir.

1 Q. Okay. Then you go to the 15th step, which
2 is, again, desiccation/drying for one hour, which is
3 that vacuum drying?

4 A. Yes, sir.

5 Q. Again, there is SEM, FTIR, light
6 microscopy, correct?

7 A. At my lab, yes, sir.

8 Q. And then there's the 16th step, which is a
9 repeat of the 12th step, correct?

10 A. Okay. Let's see. Yes.

11 Q. And then there's the 17th step, which this
12 is a new one. This is something that you haven't
13 done before. What is it?

14 A. It's using Proteinase K, an enzyme to help
15 break apart proteins.

16 Q. Okay. Now, why would you use the
17 Proteinase K at this stage in the 17th step? How
18 did you select that?

19 A. Well, if you think of the logic here, you
20 start off with flesh and fiber, and we're working
21 our way toward the surface of the explant. And when
22 we will kind of get to the surface of the explant,
23 that's where we find the strongly-adhered proteins
24 that I talked to you about. They are saying to
25 themselves, "I like it here. I don't want to go

1 anywhere."

2 So we use Proteinase K as a means to --
3 it's an enzyme, which is a little different cleaning
4 mechanism to try to attempt to get rid of the last
5 vestiges of proteins on the surface of the explant.

6 Q. This is going to sound stupid, but I'm
7 going to ask it anyway. Is the bond, where things
8 bond together, is the bond strongest where the bond
9 is actually together versus kind of back away from
10 the bond?

11 A. Well, you're asking a very good question.
12 You're asking me the difference between a cohesive
13 bond and an adhesive bond.

14 Q. Okay.

15 A. The cohesive bond is the formation of the
16 bond between the proteins themselves, and that's
17 part of what we're having to break apart.

18 The adhesive bond is the bond between the
19 proteins and the fiber. We're attempting to break
20 both of those.

21 Q. All right. So these bonds that are the
22 hardest to break are the cohesive bonds?

23 A. Well, not necessarily. I have not
24 measured that. In order to give you an exact
25 scientific measurement, I would have to do a

1 measurement. But they are very strong. Both of
2 them are strong.

3 Q. Okay.

4 A. And I have to get through that cohesive
5 bond to get to the surface of the fiber with my
6 Proteinase K before I finally can wash the last
7 vestiges off.

8 Q. Okay. So is it a fair statement to say
9 that Proteinase K is a stronger -- I'm at a loss for
10 my words -- cleaner than bleach would be?

11 A. I don't think it -- that's a different
12 one.

13 Q. It's different?

14 A. It's different.

15 Q. It might do some things that the bleach
16 didn't do?

17 A. Yes, sir.

18 Q. So, now, if we go the 17th step, that's
19 the Proteinase K followed by a water bath, and then
20 the 18th step is more Proteinase K with an
21 ultrasonic bath?

22 A. Right.

23 Q. Why did you do that?

24 A. Well, because we wanted to follow it with
25 17. You take it out, and you put it back into a new

1 bath, which is not contaminated now from anything
2 that might have come off from the 17th step. Now
3 it's in a new bath to finally do the same thing.

4 Q. Okay. Then we go back to the 19th step,
5 which is what?

6 A. Distilled water and an ultrasonic bath for
7 a one-hour rinse, and then they desiccated it in the
8 20th step and one hour drying, and they sent it to
9 me.

10 Q. Okay.

11 A. If you'll notice the last steps before we
12 come to the send to me, they try to clean it and get
13 whatever residue might have been on there off of it
14 and then dry it.

15 Q. So you can get a good picture?

16 A. That is correct.

17 Q. They know before they send it to you that
18 you're going to be doing light microscopy, FTIR, and
19 they want you to have as good as a sample as
20 possible to look at?

21 A. That's correct.

22 Q. And FTIR, doesn't that look at the
23 surface?

24 A. Yes, sir.

25 Q. So if there's a bunch of gunk on the

1 surface, FTIR might not be as reliable as you would
2 want it?

3 A. Well, we do transmission, which means it
4 goes through the sample that we're looking at. But
5 if you have a lot of, as you put it, gunk on the
6 surface, it's not what you really want to look at.
7 Then that's what you're going to get a big picture
8 of, and it's going to obscure other things that you
9 really want to see.

10 Q. Right. So the 21st step is more
11 distilled -- another long distilled water bath of
12 eight hours?

13 A. Correct.

14 Q. Are you able to do a little less time now
15 because you've cleaned off so much of it?

16 A. Yes, sir.

17 Q. And then the 22nd step is more bleach in a
18 shaker for 18 hours?

19 A. Yes, sir.

20 Q. Now, one thing, it seems like -- is this
21 your longest shaker with bleach?

22 A. I'll have to look.

23 Q. It looks like -- usually your longer times
24 are more with -- well, there's one with
25 Proteinase K. Usually the longer ones seem to be

1 with water.

2 Is there any reason why at this step
3 you're going with more bleach in the shaker for a
4 longer period of time?

5 A. Well, we've used Proteinase K. It has
6 worked a different method and opened up some of the
7 proteins, denatured them, and then we want to come
8 in there and make sure we get those off. So that's
9 why we use the shaker, because now we're getting
10 down to the real tough guys that are adhered
11 strongly to the surface.

12 Q. Now, it says the 23rd step is more bleach
13 and an ultrasonic bath for two hours, correct?

14 A. Yes, sir.

15 Q. And then your final -- or the 24th step is
16 distilled water rinse, ultrasonic bath, one hour and
17 then rinse again?

18 A. That's correct.

19 Q. And that's pretty much the final cleaning.
20 And then it goes to dry, and then you look at it and
21 you take your final pictures?

22 A. Yes, sir.

23 Q. Now, the bonds that are formed between
24 this cross-linked formalin and protein, where it is
25 adhering to the surface of the polypropylene, is

1 that a strong bond?

2 A. Yes, sir.

3 Q. Is it the type of bond where if somehow
4 they were still bound together and the protein was
5 removed, could it pull some of the polypropylene
6 with it?

7 A. That's possible.

8 Q. If the -- if -- and this is a
9 hypothetical. I know you disagree with this. If
10 the polypropylene on the surface was degraded, would
11 it be easier to pull off with this strong bond that
12 had been formed with the protein and the
13 formaldehyde?

14 A. At that particular site, that might be the
15 case. It's possible.

16 Now, you have to remember, by the time we
17 get to here, we've basically cleaned the sample, and
18 we've taken FTIRs and SEMs and light microscopy of
19 these samples all the way. So we can follow what's
20 happening. And it's not like we would have missed
21 anything on the surface of that explant if it were
22 there because what you just described happened.

23 That's why we've done all of these tests
24 at every step of the way. We plotted them all:
25 One, two, three, four, five. And in these reports,

1 you have FTIRs. After each of these steps, you have
2 light microscopy after them, and you have SEMs after
3 each of the steps.

4 Q. Let me -- I'm going to do a drawing here.

5 (EXHIBIT NO. 6 MARKED.)

6 BY MR. MONSOUR:

7 Q. Now, I'm about as good of an artist as I
8 am a polymer chemist. Okay?

9 A. Okay.

10 Q. So I'm going to draw a cross-section of a
11 Prolene fiber. This is my cross-section of a
12 Prolene fiber. Okay?

13 A. Got you.

14 Q. If there was an outer later on the surface
15 that was degraded, oxidized polypropylene, and if it
16 was removed in the process, if that happened, it
17 would, in theory, give the polypropylene implant a
18 smaller diameter if that took place, correct?

19 MR. HUTCHINSON: Object to form.

20 THE WITNESS: If you take some of the
21 polypropylene off of the exterior surface, it
22 will reduce the diameter by the amount that
23 you took off.

24 BY MR. MONSOUR:

25 Q. And so I'm going to say "before," and then

1 I'm going to say "after." And I'm going to write at
2 the top "hypothetical," because I know you disagree
3 with this, "hypothetical."

4 So you see my diagram, which is, in
5 theory -- here, I'll call it "cross-section of
6 Prolene fiber."

7 Do you see my drawing?

8 A. I do.

9 Q. And you see before would be the outer, the
10 diameter, and then after would be if that outer
11 layer was removed where it would end up being.

12 Do you understand my basic premise of the
13 question?

14 A. I understand your hypothetical.

15 Q. Okay. Here's my question. If that was
16 taking place, is there a way to measure a fiber to
17 say, well, they all started off at this measurement,
18 and then when we were done cleaning, they had this
19 measurement?

20 MR. HUTCHINSON: Object to form.

21 THE WITNESS: Well, I don't know if
22 you've seen any of these fibers or not in the
23 SEMs in the pictures and looked at them
24 carefully.

25 BY MR. MONSOUR:

1 Q. I looked at the pictures, but I probably
2 don't know what I'm looking at.

3 A. Well, you'll notice that when they're
4 wrapped together, when they're knitted, there are
5 sections that are linear in nature. And then as
6 they begin to go into a knot or where they turn, the
7 diameter changes.

8 So if you try to measure diameter -- and
9 we've done this before. We've measured diameter.
10 And you're talking about 3 mills out of
11 170-some-odd. So that's not a good way to try to
12 make a determination on what you're trying to do.

13 What we've done to try to make certain
14 that this -- if this hypothetical were to occur,
15 that's why we've done light microscopy and FTIR and
16 SEM after each of these steps to make certain that
17 we're not doing it, to make certain this
18 hypothetical did not occur and we didn't find it.

19 Q. Okay. And I understand that. But my
20 question is, let's say you could get some of the
21 sample that was not, you know, one of the knotted
22 areas, and you were to take a pristine one and then
23 one that had gone through, in theory, oxidized and
24 then been cleaned. And if the oxidized cleaned one
25 had a smaller diameter than the pristine one, could

1 that be evidence of degradation that had been
2 removed?

3 A. I don't think you can use your
4 hypothetical. Because you've got to remember that
5 not only do you have knots, but you have tension on
6 the fibers. And the exemplar right out of the
7 package has not been anywhere other than through the
8 extruder. And it hasn't been in the aqueous
9 environment. It hasn't been pulled, no tensions on
10 it. You can't -- they are so small. And the
11 difference that would be made would be so small that
12 you could not get an accurate measurement of that.
13 This hypothetical will not work in real life.

14 Q. Okay. I just wanted your opinion on that.
15 And I think what you said was, was maybe the
16 diameter -- if that were to take place, the diameter
17 would be somewhere around 130, and you would be
18 looking at a reduction of -- I mean, 170, and you
19 would be looking at a reduction of maybe three?

20 A. 2 to 3 microns.

21 Q. So it would be very difficult to measure
22 that?

23 A. Oh, yeah. It would be very inaccurate.
24 You couldn't use that as a technique. And that
25 was -- we are all hypothetical here, aren't we?

1 Q. Yeah. I will go on record saying that you
2 disagree with the underlying thought process. I was
3 just getting your opinion on this.

4 A. Yes, sir.

5 Q. I know you do not agree that degradation
6 takes place. You have told me that.

7 A. In fact, we've proven that case
8 scientifically.

9 Q. I know you think you have.

10 A. It's all in the chemistry, and we will
11 show you the chemistry before this is over.

12 Q. Well, you're showing me chemistry today.
13 It's kind of good.

14 If you were going to give me a grade thus
15 far, what would you give me? Would you give me an
16 "A," or would I be more in the "C" range?

17 A. I would just have to say that I haven't
18 had enough time with you before I grade you.

19 Q. Well, we'll see. I've got about an hour
20 and a half or so or an hour. We'll see how I do.
21 Maybe I can win you over at the end.

22 A. I kind of like you, actually.

23 Q. I like you, too.

24 MR. MONSOUR: We're at break time.

25 Since I've gone through that, let's take a

1 break. I've got one more hour with you.

2 (A BREAK WAS TAKEN.)

3 MR. MONSOUR: We're back on the record.

4 Are you ready to continue, Dr. Thames?

5 THE WITNESS: Yes, I am.

6 BY MR. MONSOUR:

7 Q. You told me that thus far today it's all
8 about science. It's all about the chemistry, right?

9 A. It's all in the chemistry, sir.

10 Q. So for the chemistry that you've talked
11 about that goes all the way back to the 1940s, for
12 that chemistry to take place, you've got to have
13 formaldehyde?

14 A. Yes, sir.

15 Q. If there's no formaldehyde, then your
16 opinions based upon formaldehyde would fail,
17 correct?

18 MR. HUTCHINSON: Object to form.

19 THE WITNESS: Well, they wouldn't be
20 part of my opinions if I didn't have
21 formaldehyde.

22 BY MR. MONSOUR:

23 Q. But I guess what I'm getting at is your
24 opinions based upon the layer on the outside of the
25 Prolene being the -- you know, the coating that is

1 created by formaldehyde and protein, that can only
2 exist if that implant was put in formaldehyde,
3 correct?

4 MR. HUTCHINSON: Object to form.

5 THE WITNESS: Well, it only exists
6 because there's proteins there. Remember,
7 the first thing that went to the foreign body
8 was proteins, and that's collagen. And so
9 the formaldehyde was added after that
10 happened.

11 BY MR. MONSOUR:

12 Q. I understand the protein stuff. I guess
13 what I'm getting at is, for what you're talking
14 about, we've got to have formaldehyde?

15 MR. HUTCHINSON: Object to form.

16 THE WITNESS: You have to have
17 formaldehyde to effect the chemical reaction
18 that we've been describing that's on page 17.
19 But that does not mean that you don't have
20 strong adhesive bonds of proteins to the
21 fiber without the fixation process. That has
22 to be in place before the formaldehyde fixes
23 it.

24 BY MR. MONSOUR:

25 Q. But I guess what I'm getting at is the --

1 again, going back to regular people language, --

2 A. Yes, sir.

3 Q. -- what you're saying is there is a
4 coating on the outside of the Prolene fibers, which
5 you do see, correct?

6 A. Yes, sir.

7 Q. And in pictures we see them. And that
8 coating has cracks in it, according to you, correct?

9 A. Yes, sir.

10 Q. For that coating to form, you've got to
11 have formaldehyde?

12 MR. HUTCHINSON: Object to form.

13 THE WITNESS: Not necessarily, no, sir.

14 For the coating to form -- that forms as a
15 result of fixation, you have to have
16 formaldehyde. But if you don't have
17 formaldehyde, you still have proteins, a
18 coating formed around the explant. You still
19 have that formation, but it's different in
20 that it's not cross-linked with formaldehyde.
21 It's still there.

22 BY MR. MONSOUR:

23 Q. Okay. So --

24 A. It's there before the formaldehyde is ever
25 added, so you've got an adhered protein to this

1 fiber.

2 Q. So let's talk about that. We're going to
3 talk -- this section of the deposition is going to
4 be in situations where nothing was ever put in
5 formaldehyde. Okay?

6 A. Okay.

7 Q. So let's take formaldehyde and throw it
8 out the window.

9 If I get an explant and it's never been
10 put in formaldehyde and there is tissue that is on
11 that explant, what do I need to do to clean that
12 one?

13 A. The same process will work. You will
14 soften the flesh with water. You will use the
15 sodium hypochlorite that will take the bleach off --
16 or the bleach will take the -- excuse me -- the
17 excess tissue off. And if you use the same process,
18 it will give you a clean explant.

19 Q. What is allowing the protein flesh to bind
20 to the Prolene implant?

21 A. You remember we talked earlier about
22 cohesion and adhesion? We had this discussion in
23 the session before this. Well, there's a strong
24 adhesive bond that forms between the proteins and
25 Prolene, and that occurred -- in the last session,

1 that occurred even before formaldehyde was added.

2 That's the point I'm trying to make.

3 If you have a strong bond already formed,
4 when you add the formaldehyde, you're making it
5 stiff because, i.e., you want to preserve it, number
6 one, so that it doesn't rot; and if you're a
7 histologist, you want to make sure that it's been
8 fixed so that it's rigid enough that you can get a
9 good slice and get you a good -- material to work
10 with.

11 Q. Okay. Good.

12 So here's my next question. For the
13 formaldehyde-protein bond that you explained to me,
14 you were able to cite me some articles from the '40s
15 with Dr. Fraenkel-Conrat. Is there any authority
16 that explains the bond that forms between the
17 Prolene and the protein?

18 A. Yes, sir. And I have several of them
19 cited in this report, in the reports that you see.

20 Q. So those are cited in the report?

21 A. Yes, they are.

22 Q. Could you very quickly point me to which
23 section that is?

24 A. It may not be very quickly.

25 Q. Assume I haven't memorized your report but

1 that I have read it.

2 A. 59 and 60, 61 and 62 on page 15 of my
3 report.

4 Q. On page what?

5 A. 15 of my report. With your permission, I
6 would like to read this first sentence.

7 Q. Please do.

8 A. It is under the heading of "Protein
9 Adsorption on Implant Device Surfaces."

10 "It is well established that implantation
11 of a foreign body (mesh materials, as an example)
12 elicits a foreign body reaction involving the
13 immediate formation of tenaciously adsorbed and thus
14 adhered 'protein coating' onto the surface of the
15 implanted materials," 59, 60, 61 and 62 references.

16 Q. And you cite -- there is a Dr. Kyriakides,
17 and he's got a book. And there's chapter 5 of that
18 book, and you're citing to that?

19 A. Yes, sir. It's important that we go -- to
20 really be able to explain this, if you don't mind,
21 it's important that we look at that a little closer.
22 Is that okay?

23 Q. Sure.

24 A. Well, if we go down to about midway in
25 that paragraph, it says, K-Y-R-I-A-K-I-D-E-S,

1 "Kyriakides also states that body proteins adsorb
2 onto implanted material surfaces and contact the
3 surface even before cells reach the implant,"
4 reference 64.

5 So you've got an implant, and then you've
6 got the proteins, and then you've got the cells of
7 the human body coming in. That's all there before
8 we ever get to formaldehyde, because that's in the
9 body. Then it has to be taken out of the body as an
10 explant, put into formaldehyde, and then the
11 formaldehyde reaction takes place.

12 Q. Okay. So with regard to this, this is the
13 first bond that takes place. Then the -- I don't
14 want to get the word wrong. Then the cross-linking
15 takes place when the formaldehyde is added later?

16 A. Yes, sir.

17 Q. And I think I asked you this, but I'm not
18 for sure. Which bond is stronger, the first bond
19 that takes place, the adsorption -- that's "ad" with
20 a "D" -- adsorption of the protein onto the
21 polypropylene or the second one that takes place
22 with the formaldehyde?

23 A. I have not measured that specifically, and
24 I cannot give you a specific technical answer. But
25 I can tell you based on the cleaning protocol and

1 the information that I've read, that the bond
2 between the proteins and the -- and Prolene, which
3 is the fiber, is very strong, as is the cohesive
4 bond. They're both strong.

5 But in this cleaning process, we're
6 working on the cohesive bonds, in other words, to
7 make the bonds between the fibers break and go away
8 so that we can move the materials off of the surface
9 of the explant --

10 Q. Okay.

11 A. -- without damaging the explant.

12 Q. Another question I want to ask you, you
13 talk about this, and you talk about the staining of
14 some of Dr. Yakovlev's work when you talk about H&E
15 stains, I guess, adhering to polypropylene.

16 Do you remember that?

17 A. No. H&E stains won't adhere to
18 polypropylene.

19 Q. That's what you say in the report. You
20 say it --

21 A. That's a fact.

22 Q. -- cannot happen.

23 A. It's all in the chemistry.

24 Q. Let me ask you this: Is there a chemical
25 difference between polypropylene and oxidized

1 polypropylene?

2 A. Well, oxidized polypropylene would have an
3 oxygen atom in it. It would be a ketone, more than
4 likely. It would not be soluble in water. It would
5 not have a functional group on it that would be
6 attracted to or would react with the stain.

7 Q. So I guess you anticipated my question.

8 A. Yes, I did.

9 Q. My question is, can H&E stains, can they
10 stain oxidized polypropylene?

11 A. I don't believe they will, no, sir.

12 Q. Now, you've said, "I don't believe they
13 will." Where would we look for authority on that?
14 Because I don't believe -- you know, I don't believe
15 Texas is going to win the national championship next
16 year. That doesn't mean they're not going to.

17 So when I hear, "I don't believe," my
18 question is, where do I go for the authority as to
19 whether or not H&E stains will stick to oxidized
20 polypropylene?

21 MR. HUTCHINSON: Object to form.

22 THE WITNESS: Well, first of all, the
23 term "stick to" is not technical and has no
24 merit in this conversation, but we realize
25 that you're just using it as an analogy.

1 BY MR. MONSOUR:

2 Q. Right. I'm using regular people words.
3 You can use whatever words you want.

4 A. First of all, in order for something to
5 adhere to a stain, it has to be ionic. It has to
6 have an ionic bond. It has to have a structure if
7 it's capable of being ionic. To be ionic, it has to
8 be in water to form an ion, to be in an aqueous
9 medium.

10 Polypropylene and/or oxidized
11 polypropylene is not going to be soluble in water.
12 It is not going to have a functional group on it
13 that will ionize such that it can react with an
14 ionic species of a different charge.

15 That's what happens when you get a stain
16 to form a bond, adhere to it. That's why when you
17 wash off all the excess stains, that stays there,
18 because a chemical bond has been formed. And that's
19 why the color comes in. Okay?

20 Q. Okay.

21 A. And you won't have those functional groups
22 present if you oxidize polypropylene. And if you
23 do, it will be of such a high molecular weight that
24 it won't go into water and it won't be ionic and it
25 won't stain.

1 And I use as my authority to back up my
2 support the experiments of Dr. Steven MacLean from
3 Exponent, and that's a very recent response. And
4 they have proven that it doesn't stain. I know it
5 wouldn't stain.

6 If you look at the chemistry and you look
7 at what has to happen for a stain to adhere, to form
8 a bond, you would know that this just will not
9 stain.

10 Q. I'm just -- I know you seem incredulous
11 that I couldn't know this. I'm not real good at
12 chemistry.

13 A. I understand. But I'm just saying this
14 for the record because it's a fact, you know.

15 Q. Who is Dr. Steven MacLean?

16 A. He's a scientist that works for Exponent.
17 He's out in the San Francisco laboratory, and he
18 submitted a report.

19 MR. MONSOUR: Is he one of y'all's
20 retained experts? Is he a testifier?

21 MR. HUTCHINSON: (Nods head
22 affirmatively.)

23 BY MR. MONSOUR:

24 Q. What would you need to see, what type of
25 evidence would you need to see to -- so that it

1 could establish to you that polypropylene or Prolene
2 degrades once it's implanted in a woman
3 transvaginally?

4 MR. HUTCHINSON: Objection. Asked and
5 answered.

6 THE WITNESS: I have answered that
7 question before.

8 BY MR. MONSOUR:

9 Q. Okay.

10 A. You asked that question. And I'm not
11 being short with you, but you asked it, and I gave
12 you the answer.

13 Q. Okay. I forget.

14 A. I would need carbonyl groups formation. I
15 would then follow up with that molecular weight
16 physical property test.

17 Q. Okay, okay. As far as cleaning explanted
18 medical devices and prostheses, is there any
19 textbook or authority that you would rely upon?

20 A. Well, first of all, the only medical
21 device that I was interested in cleaning was
22 Prolene, not anything else.

23 Q. Okay.

24 A. So when you look at Prolene, you look at a
25 fiber, you look at the fact that it has a melting

1 point, you look at the fact that it softens, and you
2 are saying, well, I'm going to be looking at this
3 because people are going to be asking me, well, does
4 this material oxidize or not? That's the key
5 question. Does it oxidize? Does it degrade?
6 Should it be in the human body? And I've got to
7 find out whether that's the case or not.

8 So I select a protocol understanding the
9 chemistry of where that explant came from. See, I
10 look at it in totality. Where did it come from? It
11 came from the human body. Well, what's on it?
12 Flesh. Well, what else? Well, when they got
13 through taking it out, they dropped it in some
14 formaldehyde. And guess what? Flesh has proteins
15 in it, and proteins react with formaldehyde, and it
16 forms a hard matrix around it. I've got to get that
17 off. But I don't want to do anything to damage the
18 implant. How do I do that? Well, I just reverse
19 the reaction that caused it to form in the first
20 place, and then I use a little Clorox along the way
21 to get the flesh out of the way.

22 And when I do that, after every step I
23 look at the light microscopy, I look at the scanning
24 electron microscopy, and I look at an FTIR to see if
25 there are any carbonyl groups there. If there are

1 no carbonyl groups there, then there's no oxidation.

2 Q. That's one of the things I was going to
3 ask you about. And this is -- again, this is going
4 to go back to my ignorance in chemistry.

5 But when you were talking about looking --
6 using FTIR to spot carbonyl groups at the 1730, 1750
7 range, do you remember us talking about that?

8 A. I do, sir.

9 Q. And you said when you find it and it
10 becomes positive, one of the things that it could be
11 positive for, if it was there, is it could be for
12 degraded polypropylene, but it could be for maybe
13 calcium stearate or for DLTDP, right?

14 A. Yes, sir.

15 Q. Are there amounts of those components that
16 you would need to see for it to show up on FTIR?

17 A. Well, I haven't done a study where I say,
18 okay, Ethicon, I want you to make Prolene with
19 .1 percent by weight of DLTDP and then by .2 percent
20 by weight and then .3 percent by weight.

21 In order to answer your question and be
22 very precise, I would need to know that. All right.
23 And, of course, after each of those, I would look at
24 the FTIR.

25 But I have found DLTDP and FTIRs of

1 exemplars and found that as we clean them, that
2 diminishes somewhat because we're using bleach and
3 we're using water.

4 So I can't give you a specific technical
5 answer to your question.

6 Q. Okay. So let me ask you this: Why as you
7 use bleach and water do you think there would be
8 less and less DLTDP?

9 A. Well, it would be oxidized.

10 Q. What's "oxidized"?

11 A. The DLTDP, and hydrolyzed. It's an ester.

12 Q. Okay.

13 A. Esters hydrolyze in water.

14 Q. And so the water is causing the DLTDP to
15 oxidize?

16 MR. HUTCHINSON: Object to form.

17 THE WITNESS: The water and the
18 environment it's in is causing a reduction in
19 the concentration of DLTDP.

20 BY MR. MONSOUR:

21 Q. And DLTDP is an antioxidant, right?

22 A. Yes, sir.

23 Q. So I just want to ask my question clearly.
24 You kind of answered it, but I want to make sure I
25 get this clearly.

1 How much DLTDP needs to be in a Prolene
2 fiber for it to show up on FTIR?

3 A. I've answered that question.

4 Q. And the answer is you don't really know?

5 A. No, I don't. Because I haven't done a
6 quantitative measurement to know exactly the amount
7 that needs to be there before I will pick it up on
8 my FTIR instrument.

9 Q. Right. But then that gets back to my
10 question. Wouldn't you need to know that? Because
11 what I -- you're trying to teach me good science,
12 and I'm wanting to be a good student here. I want
13 an "A." I want an A-plus.

14 A. You better hurry.

15 Q. I'm wanting an A-plus.

16 So my question is, if you're kind of
17 ruling in as a possible that DLTDP could be what's
18 making the FTIR show up between 1730 and 1750,
19 wouldn't you need to know as a scientist how much
20 DLTDP would have to be there for it to ping
21 positive?

22 A. Well, that would be helpful. But at the
23 same time, what we see happening as we clean this is
24 that DLTDP is lost, and there's still no carbonyl
25 groups. And that's not -- and it doesn't show up in

1 every one of them, by the way.

2 We're talking here like there's an
3 assumption that every one of these fibers shows
4 DLTDP, and it doesn't.

5 Q. Okay.

6 A. But what should be present, if we have
7 oxidized polypropylene, is we should always have a
8 carbonyl peak, and that carbonyl peak should not go
9 away in this cleaning process.

10 Q. All right. Let me ask you about a calcium
11 stearate.

12 A. Yes, sir.

13 Q. How much calcium stearate would need to be
14 present in a Prolene strand so it could, you know,
15 show positive on FTIR between 1730 and 1750?

16 A. Same answer that I gave you for DLTPD.

17 Q. And the answer to that is you're not
18 really sure, correct?

19 A. That's correct from a very specific point
20 of view.

21 Q. So tell me, what is the purpose of DLTPD?
22 Tell me what an antioxidant does.

23 A. Well, if there's a free radical formed,
24 the oxi- -- the theory is that free radicals are
25 formed, and then they form hydroperoxides, and they

1 decompose. And then the decomposition process, it
2 breaks the bond of a Prolene species and produces a
3 ketone or an aldehyde. And that's where a C=O would
4 be made during the oxidation process. And that's
5 what we should be seeing occurring on the explant
6 fibers when we look at it in our FTIR.

7 Q. So let me ask this question. Prolene is a
8 polypropylene that has had antioxidants added to it,
9 right?

10 A. Correct, and some other things.

11 Q. If you took just pure polypropylene
12 without the additives, would it degrade through
13 oxidative degradation?

14 A. It depends upon how much -- how you did
15 the degradation. All of this is, what did you
16 subject the material to? It's well known that
17 polypropylene will degrade in thermal energy. You
18 know, it has a -- it starts degrading at 333 degrees
19 Centigrade, which is 600-and-something degrees
20 Fahrenheit. Well, that's an unrealistic number for
21 what we're talking about here.

22 Q. Right, absolutely.

23 A. It's also known that UV light will degrade
24 polypropylene even more readily than energy. So
25 polypropylene will degrade, and I've said that

1 clearly in my report.

2 Q. Okay.

3 A. But what we're talking about is, does it
4 degrade in the environment that we're talking about?
5 And the answer is "no."

6 Q. What about when it's exposed to reactive
7 oxidative species?

8 A. Well, that's been a --

9 MR. HUTCHINSON: Excuse me. Object to
10 form. Are you talking about Prolene or
11 polypropylene, Counsel?

12 MR. MONSOUR: Prolene.

13 THE WITNESS: Thank you. That's the way
14 I understood you to mean.

15 No one has determined or made a
16 determination of the fact that reactive
17 oxidative species oxidizes polypropylene, to my
18 knowledge. I have not seen that anywhere. I
19 know that has been thrown out as a
20 hypothetical, but it's never been proven.

21 BY MR. MONSOUR:

22 Q. Okay. So let me ask you this: What would
23 you need to see to have it established to you that
24 reactive oxidative species could cause degradation
25 in either Prolene or another polypropylene that had

1 antioxidants added to it?

2 A. Well, the question that you asked me
3 broadens out the concepts of what we're talking
4 about here.

5 When you're saying, well, what would I
6 need, the implication is, is there some kind of test
7 that you could run that would satisfy you that
8 reactive oxidative species will oxidize Prolene.
9 Well, we're talking about an accelerated test in an
10 environment that Prolene is not in.

11 The only way to do what you're talking
12 about is to have Prolene in a human body or in an
13 animal where there's excessive reactive species and
14 then evaluate the explant as it's removed.
15 Otherwise, we're talking about an accelerated test,
16 a different environment. And I don't know how you
17 achieve that.

18 I mean, I know that Dr. Priddy has tried
19 accelerated tests, and they don't work. And the
20 reason is there's what's called a transition state,
21 and the transition state is if you start out with
22 two species, A and B.

23 In our case, those two species would be
24 reactive oxidative species and Prolene, and they're
25 hitting each other. They're there. The chemicals

1 react. But what happens as a result of their
2 contact? In order for us to produce, as you want to
3 say, a carbonyl group, there's a certain amount of
4 energy that is required to go up to the transition
5 state before it can go into the final products over
6 here.

7 And I have not seen any case where there's
8 been any carbonyl group formation. And, therefore,
9 I don't ever think the activation energy required
10 has been reached. No one has shown that.

11 Q. When you look at explants and the level of
12 DLTPD has dropped or has lessened, does that
13 indicate to you that the antioxidant is working as
14 it's intended?

15 A. Well, when you say when I look at an
16 explant, keep in mind that what we're doing is we
17 have one small piece of fiber, and it's round and
18 that we're putting a light through it. And
19 sometimes that light beam may be on the -- this
20 is -- I'm taking a bottle and laying it on its side.
21 If the light beam comes and hits over here, then the
22 transmission is a shorter wavelength. If it hits
23 here -- excuse me. It hits through more of the
24 material than if it's over here.

25 And it depends on the orientation

1 sometimes as to whether you see DLTDP or not. That
2 doesn't mean it's not there. Okay?

3 Q. Okay.

4 A. So...

5 Q. No, I guess that's not my point.

6 My point is, are you basically saying that
7 the DLTDP is functioning as an antioxidant with
8 regard to light?

9 A. Yes.

10 Q. Okay.

11 A. And in the body, in a person's body, as
12 we're talking about here, it's an antioxidant and a
13 very good one.

14 Q. Was the -- and you might not know the
15 answer to this. Was the antioxidant package for
16 Prolene, was it designed for -- were the
17 antioxidants selected based upon needs for
18 implantation in the human body or needs based upon
19 thermal processing? Do you know?

20 MR. HUTCHINSON: Objection.

21 Speculation.

22 THE WITNESS: Oxidation is oxidation,
23 but it just depends on what it means. You
24 can have a product designed for high energy.
25 And that's one of the things that Santonox R

1 was put in for, because it's more for
2 processing than -- you have to put
3 polypropylene under a pressure to extrude it
4 out of the extruder, and it has to be at high
5 energy so it's melted. And you don't want it
6 to oxidize there. So it's there as well as
7 is DLTDP.

8 So they're put there, number one, to make
9 certain that during the processing stage you
10 don't get oxidation. And my logic would be,
11 well, certainly, if you don't get oxidation
12 during that processing stage, how would you
13 expect to ever get it in the human body? You
14 just think about that from a simplistic point
15 of view here.

16 BY MR. MONSOUR:

17 Q. That's what I've got to do. You can't
18 make it too hard or I'll be all confused.

19 A. Well, here you've got this extruder, and
20 I'm holding this bottle up, and you're pushing the
21 Prolene, the polypropylene, not pro- -- all right.
22 You're pushing it through and -- but it does have
23 the materials in it that make it Prolene. And
24 you're pushing it through, and it's under high
25 energy, and it's in a very flexible state. Oxygen

1 is all around it, but it doesn't oxidize.

2 Why in the world would it, if it doesn't
3 oxidize there, would it oxidize in the body with a
4 reactive oxidative species present?

5 Q. Well, let me ask you this: Do they ever
6 look at polypropylene that's pristine to see if
7 there's any degradation on the outside of it to --
8 through the processing of it?

9 MR. HUTCHINSON: Object to form.

10 THE WITNESS: Well, let me answer that
11 this way. I have looked at many, many
12 exemplars of polypropylene, and there's never
13 been any oxidation on the surface of it.

14 BY MR. MONSOUR:

15 Q. What have you looked for?

16 A. To see what it looked like. To give a
17 control spectra. It's a control.

18 Q. Hold on. I think I read something that
19 talks about that. Dr. Thames, I could swear I saw
20 something about this.

21 What's "melt spinning"?

22 A. You melt it and you spin it into a fiber.

23 Q. Is that different than -- is that how they
24 do Prolene?

25 A. They extrude Prolene, and it comes out as

1 a fiber.

2 Q. So Prolene is extruded?

3 A. Yes, sir.

4 Q. And melt spinning is a different process?

5 A. That's my understanding. You could melt
6 spin the fiber. You could do that, and I'm not sure
7 whether they do that or not, but it could be done.

8 Q. How would you -- I'm going to ask you some
9 questions while she's reading through that.

10 You do not believe there is any pristine,
11 new Prolene or polypropylene with additives fibers,
12 as they're extruded, you don't think there would be
13 any surface oxidation at all?

14 A. No, sir. Well, let me back up. When you
15 said "at all," I can't say there's not one molecule
16 of oxidation. But for practical purposes, there is
17 no oxidation, and I'll tell you why.

18 I know this. Every piece of Prolene that
19 I've looked at, and I've done all the exemplars, it
20 has never had any oxidation on the surface. So what
21 they're selling for implantation in human beings
22 doesn't have oxidation on the surface.

23 Q. Now, does Prolene have any antioxidants
24 other than Santonox R and DLTDP?

25 A. No, sir.

1 Q. Just those two?

2 A. Yes, sir.

3 Q. And they're both intended or used for
4 thermal processing?

5 A. Yes. Santonox R is primarily used to be
6 there for the thermal processing, and DLTDP is there
7 for that as well. They both are UV inhibitors -- or
8 antioxidants. Excuse me.

9 But the principal one during the spinning
10 process or melting process -- extruding process, I
11 mean, is Santonox R.

12 Q. Okay. Do you know a Dr. Guidoin?

13 A. Robert?

14 Q. Yeah.

15 A. I don't know him, but I know him by his
16 involvement. I'm not sure if he's still alive or
17 not. I don't know. But I do know him by his
18 involvement here. He's the one I referenced that
19 did the paper on the difficulty in removing
20 everything. So, in that regard, yes, I know him.

21 Q. And he has also done some testing on some
22 Prolene explants over the -- or been involved to
23 some extent?

24 A. He's provided -- I know he provided a lot
25 of explants to Ethicon for them to test, and they

1 did so as they received it as is, if you remember.

2 Q. Do you know how he cleaned the explants?

3 A. I'm not sure.

4 Q. Would you look at his cleaning techniques
5 as being authoritative?

6 MR. HUTCHINSON: Object to form.

7 BY MR. MONSOUR:

8 Q. Or reliable?

9 MR. HUTCHINSON: Same objection.

10 THE WITNESS: I don't know what his
11 cleaning technique is, other than maybe
12 washing it in sodium hypochlorite. I have
13 not seen a technique that he's put together
14 like the one I have here. I just know what
15 his article said and how he felt the
16 difficulty in cleaning them was.

17 And I do know that the explants that he
18 has provided to Ethicon were labeled "as is"
19 implication; therefore, they have not been
20 cleaned and been through a cleaning process
21 like this. And, of course, the data that was
22 achieved from the people who evaluated those
23 "as is" implants showed there were fibers
24 fleshed out.

25 BY MR. MONSOUR:

1 Q. Are you talking about the dog study?

2 A. No.

3 Q. Which one are you talking about?

4 A. That's not necessarily a study. But they
5 were looking at -- "they" being Ethicon -- was
6 looking at a lot of explants to look at this issue
7 of, well, people are saying maybe we've got some
8 oxidation here. Is it happening? And then the
9 answer is "no."

10 And they were looking at all sorts of
11 implants to determine whether there had been
12 oxidation and could prove it was there. And the
13 answer was "no." And he provided them a lot of
14 explants. And when he provided it to them, it was
15 labeled -- and they said, "Well, we will evaluate it
16 'as is,'" meaning here it is. I'm not going to do
17 anything to it.

18 And when I see something that is "as is,"
19 okay, there it is. I'm going to evaluate it like it
20 is.

21 Q. The dog study you're familiar with,
22 correct?

23 A. I am. Yes, I am.

24 Q. Your counsel really likes the dog study.

25 A. I do too.

1 Q. Tell me why you like the dog study so
2 much.

3 A. Well, it's a seven-year study. The
4 beautiful part of it is it was set out to determine
5 exactly what we're talking about today. Do we have
6 oxidation taking place? Do we have damage to the
7 implants taking place?

8 Let's go to like -- and, you know, you
9 asked me earlier how I would go do certain things.
10 And I said I would have to put it in a human body or
11 in an animal and evaluate it over a long period of
12 time so that we could see what kind of reactive
13 oxidative species were really there.

14 Well, as they did the dog study, at
15 intervals they would take a dog and euthanize it and
16 take the sutures out, the Prolene sutures, and they
17 would evaluate it. Then the evaluation that I
18 really liked was they would do the mechanical study.
19 They would do the tensile strength, elongation, and
20 then you could look at toughness. They also did
21 molecular weights.

22 And what I described to you earlier is
23 that in order to have degradation, you've got to
24 have loss of molecular weight, and you've got to
25 have loss in mechanical/physical properties.

1 There's no question about that. That is not an
2 argument. It's written in every paper you'll get
3 to, every scientific document. It's not Shelbyism;
4 it's scientism.

5 Q. Okay.

6 A. So they did that, and they did that in
7 intervals. And when they finally got -- and every
8 time they were doing the molecular weight, molecular
9 weight, molecular weight, tensile strength, tensile
10 strength, tensile strength, elongation. And they
11 got all of that data, and they plotted it.

12 Do you know what they found out? They
13 didn't have any loss of molecular weight after seven
14 years. And they also found out that the implants --
15 that the Prolene improved toughness over that
16 seven-year time, so they got stronger and tougher.

17 So that would not be the case under any
18 circumstances had there been degradation to cause
19 molecular weight loss. You would never have gotten
20 those kind of results.

21 Q. Okay. Now, you had mentioned some ASTM
22 testing that was done before --

23 A. Uh-huh (affirmative response).

24 Q. -- where you have to have five samples.

25 A. Yes.

1 Q. How many samples did they have in the dog
2 testing?

3 A. My understanding is they used the ASTM
4 testing. They used five multiple samples.

5 Q. So they did have five?

6 A. That's my understanding.

7 Q. As far as the loss of -- there not being a
8 loss of molecular weight in the dog study, do you
9 know how they measured that?

10 A. GPC. As a matter of fact, one of your
11 witnesses has done about almost 20 GPC analyses of
12 explants and found no loss of molecular weight.

13 Q. Who is that?

14 A. Dr. Jordi. And, of course, these
15 gentlemen at Ethicon did their molecular weights.
16 And he has testified that there was no loss in
17 molecular weight.

18 Q. Is there any other way to measure a loss
19 of molecular weight other than GPC?

20 A. Well, that's considered the gold standard.
21 And why would you go away from the gold standard?

22 Q. I don't know, unless there's a platinum
23 standard.

24 A. No, huh-uh. We're talking about the gold
25 standard here.

1 Q. A diamond standard? I don't know.

2 A. Well, plants sometimes use viscosity
3 measurements as -- they'll run a series of tests
4 where we're going to make this polymer, and this
5 polymer has to have a certain viscosity if it's
6 maintained its molecular weight and so forth.

7 And so they'll do their control, their
8 quality control based on viscosity because it's a
9 lot easier, a lot simpler to run viscosity
10 measurements than it is GPC measurements. But those
11 viscosity measurements were determined by GPC
12 measurements early on.

13 Do you follow me?

14 Q. No.

15 A. Okay. Before they made a determination on
16 what a viscosity needed to be to produce a product
17 that they wanted to have the properties that they
18 wanted to have, they had to first determine, well,
19 what is the molecular weight at this viscosity, at
20 this viscosity, at this viscosity? And so they
21 determined that at viscosity you had a certain
22 molecular weight. And they measured it based on
23 that, on the viscosity.

24 If the viscosity is too high or too low,
25 the one they pinpointed, then they need to change

1 the -- you know, their system is out of control, and
2 then you get it back in control. That's the quick
3 way to do it. That's the way a production plant
4 might do it.

5 Q. Okay. Toughness, --

6 A. Yes, sir.

7 Q. -- it's been mentioned with regard to the
8 dog study. And I think you've got a section in your
9 report about that.

10 How do you measure toughness, and how did
11 they do it in the dog study?

12 A. Well, toughness is the area under the
13 curve when you have tensile strength and elongation
14 measurements. Let's get back to this. Let's go
15 show you that. I'm not sure what page that's on,
16 but we'll try to -- I think it should be fairly
17 early in the report.

18 Q. I think it is. That is page 8.

19 A. Yes, sir. If you see that -- the vertical
20 axis is breaking strength. It's called tensile
21 strength. And what they're doing is they're taking
22 this material and putting it in an MTS, a strand of
23 fiber. And they're pulling it, and they're pulling
24 it at a certain speed, and it ultimately breaks.
25 When it breaks, that's ultimate tensile strength,

1 and that's what they're measuring.

2 Well, while they're pulling it to break
3 it, they also are elongating it, and they're
4 measuring elongation at the same time. So they get
5 these two numbers, and they plot them. Elongation
6 is a function of tensile strength.

7 And you'll notice the red part. This was
8 the -- this is the control at year zero. Okay?
9 Elongation at 1.6 pounds is 37 percent. That's
10 tensile strength. The tensile strength is
11 1.68 pounds that they had when it finally broke.

12 You see your chart right here?

13 Q. So it breaks here?

14 A. Right here.

15 Q. Right there?

16 A. Yes, sir. And this line just goes down to
17 show you --

18 Q. Where it is?

19 A. -- where it is.

20 Q. Okay.

21 A. And then the same thing is while you were
22 putting that much force on the fiber, it was
23 elongating over here to after year seven -- well, in
24 this case, the elongation was 37 percent, and this
25 is the tensile strength.

1 Q. So if I look at this chart, basically what
2 it shows is the control versus the year seven --

3 A. Yes, sir.

4 Q. -- one, it was -- it looks like the break
5 strength from the control to year seven dropped a
6 little bit, from like 1.65 to 1.7 down to 1.6,
7 right?

8 A. 1.68 is the pounds.

9 Q. Okay. 1.68 --

10 A. To 1.6.

11 Q. -- to 1.6. But the elongation increased
12 from 37 to 78.

13 A. That's correct.

14 Q. So the area underneath the curve, the blue
15 curve, versus the area underneath the red curve is
16 the toughness. And you're saying that because the
17 area underneath the blue curve is so much bigger,
18 it's tougher than the area underneath the red curve?

19 A. That's how it's measured, yes, sir.

20 Q. Now, here's my question. Can you explain
21 to me how that could happen?

22 A. Yes, sir, I absolutely can. When you
23 implant polypropylene into a human body, it is
24 surrounded by tissue, which is made up of fats and
25 oils, triglycerides. You know, we go get our blood

1 tested to see how much triglycerides, how much
2 cholesterol we've got in our body. So we know they
3 are there. And these are materials that are lower
4 molecular weight, and these are materials that have
5 an affinity for something like Prolene because it's
6 a hydrocarbon material. And they function and they
7 move into Prolene, and they become plasticizers.

8 A plasticizer is a material that will
9 allow something to be more pliable. And for the
10 young lady over here, sometimes you use hand cream
11 because your hands have gotten a little dry and
12 you're afraid they will crack and you don't want
13 that. You want your hands to look supple and soft.
14 So you use hand cream, which is a plasticizer, which
15 moves into your hands and plasticizes your skin, and
16 it becomes very soft. In our case, that's exactly
17 what happened.

18 And then when you talk about pulling
19 strings this way, if you just think about it from a
20 very simplistic point of view now, simple, you
21 wanted me to talk simplicity, if you took -- those
22 materials are acting as lubricants for the fibers.
23 So if the lubricant is not there, it will pull and
24 pull and then snap. That's the first elongation
25 case.

1 But after implantation and the
2 plasticization of the environment, you've got the
3 elongation. So, actually, from a functional point
4 of view, it improved over time.

5 Q. Kind of like if you put boot cream on Red
6 Wing boots?

7 A. Absolutely. They're hard as a rock, and
8 you want to make them softer.

9 Q. Okay. I'm going to ask you a couple more
10 questions on plasticization, and then I'm going to
11 be done.

12 A. Okay.

13 Q. Now, as far as your theory on
14 plasticization --

15 A. Well, it's not my theory.

16 Q. Okay.

17 A. This is well established. The concept of
18 plasticization is well established.

19 Q. Let me ask you this question.

20 A. All right.

21 Q. Let me ask this question, then. In the
22 dog study, that was a study done by Burkley.

23 A. Yes, sir.

24 Q. B-U-R-K-L-E-Y.

25 Did Dr. Burkley conclude that oxidative

1 degradation took place?

2 A. He indicated that there might be some
3 oxidative degradation, and he was wrong. Because if
4 there had been, you would not see a curve like this.
5 It's impossible to have oxidative degradation and
6 have that curve of physical properties and no loss
7 in molecular weight.

8 Q. Okay.

9 A. They go together. It's like being married
10 and having your first child. You know, carbonyl
11 group formation, loss in molecular weight and
12 physical properties, they all go together.

13 Q. I'm going to quote you later on about that
14 for a point that I frequently made.

15 But I would like -- so Dr. Burkley -- did
16 Dr. Burkley ever conclude that plasticization had
17 taken place?

18 A. I don't think he referred to
19 plasticization, as far as I can remember.

20 Q. Did he ever refer to anything similar to
21 plasticization?

22 A. Not that I can remember.

23 Q. Did he ever refer to increased toughness?

24 A. Not that I can remember.

25 Q. Okay. So I'm just going to ask you this,

1 and you might not know the answer.

2 A. Okay.

3 Q. But Dr. Burkley has got all this data in
4 front of him, and he's specifically there looking to
5 see whether or not there's oxidative degradation,
6 correct?

7 A. That's correct.

8 Q. I mean, that's the whole point of his
9 tests, right?

10 A. Uh-huh (affirmative response).

11 Q. Right?

12 A. Correct.

13 Q. If that's the point, and the issue of --
14 or plasticization is well known, and toughness is
15 well known, and he's got all the data in front of
16 him, how did he not get to where you got?

17 MR. HUTCHINSON: Objection.

18 Speculation.

19 THE WITNESS: He was a very young
20 scientist at that time, and I'm not sure what
21 his polymer background was.

22 BY MR. MONSOUR:

23 Q. Is it a fair statement for you to say -- I
24 want to summarize your opinion and see if you agree
25 with me.

1 Dr. Burkley had all the data he needed.
2 He just missed it and misinterpreted it?

3 A. This is no reflection on Dr. Burkley, but
4 yes, that's the answer.

5 MR. MONSOUR: Okay. I have used up my
6 three hours. I am done with your general
7 deposition at this point in time.

8 EXAMINATION

9 BY MR. HUTCHINSON:

10 Q. Dr. Thames, Chad Hutchinson, counsel for
11 Ethicon. I have a couple follow-up questions.

12 If you'll turn with me, please, to page
13 100 of your report, this is your general report; is
14 that right?

15 A. That is correct, sir.

16 Q. If you look on page 100, it shows the
17 cleaning protocol that you were asked about; is that
18 right?

19 A. That's correct.

20 Q. Under the cleaning protocol, it states,
21 "Figure 33, Patient 4 Cleaning Protocol."

22 Did I read that correctly?

23 A. You did, sir.

24 Q. Now, Dr. Thames, is patient 4 part of the
25 20 case-specific reports?

1 A. No, sir.

2 Q. Dr. Thames, does the title under the
3 cleaning protocol on page 100 say, "This is the
4 exact protocol that was used with all 20
5 case-specific explants"?

6 A. Where are you looking at?

7 Q. (Indicating.)

8 A. No, sir.

9 Q. And do the case-specific reports that you
10 did now include the correct cleaning protocol that
11 was used with those plaintiffs?

12 A. Yes.

13 Q. Dr. Thames, is there anything at all wrong
14 about this cleaning protocol?

15 A. Not at all.

16 Q. Is it just an example of an older cleaning
17 protocol that you have used on what we have called
18 patient 4?

19 A. Absolutely.

20 Q. And, in fact, are you giving patient 4 as
21 an example of an explant that has been cleaned here
22 in your report?

23 A. Yes.

24 Q. And did you provide some images from
25 patient 4?

1 A. I did.

2 Q. And if you're giving patient 4 as an
3 example of an explant, wouldn't you want to show the
4 cleaning protocol that you used for that explant?

5 A. I would.

6 Q. And is that what you were doing here on
7 page 100?

8 A. Yes.

9 Q. Did it work on patient 4?

10 A. Yes, sir.

11 MR. HUTCHINSON: I don't have any
12 further questions.

13 MR. MONSOUR: A real quick follow-up.

14 FURTHER EXAMINATION

15 BY MR. MONSOUR:

16 Q. Was the protocol that you used that's on
17 page 100 of your report, was that done to clean
18 protein and flesh off of a Prolene implant?

19 A. Yes, sir.

20 Q. Was it done in connection with the
21 transvaginal mesh litigation?

22 A. Yes, sir.

23 Q. Would you remember the name of the patient
24 off the top of your head?

25 A. Yes, sir.

1 Q. Who was it?

2 A. Ramirez.

3 MR. MONSOUR: Okay. That's all I have.

4 MR. HUTCHINSON: Just one quick
5 question.

6 FURTHER EXAMINATION

7 BY MR. HUTCHINSON:

8 Q. Dr. Thames, you were asked questions about
9 seeing that DLTDP is lost during the cleaning
10 process.

11 A. Yes, sir.

12 Q. Do you remember that?

13 A. I do.

14 Q. Why?

15 A. Why would it be lost?

16 Q. Correct.

17 A. If it's lost, it's lost because of the
18 cleaning process itself. It's under temperature.

19 DLTDP is an ester. Esters will hydrolyze.
20 This is 70 degrees Centigrade in an aqueous
21 environment, and you have sodium hypochlorite in
22 portions of that. And that is an environment that
23 will hydrolyze esters and would certainly not be in
24 the body.

25 It wouldn't be in the body. There's no

1 70 degrees in the body, and there's no sodium
2 hypochlorite that we've added in the body.

3 MR. HUTCHINSON: Okay. Thank you.

4 (CONCLUDED AT 11:45 A.M.)

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

1 CERTIFICATE OF COURT REPORTER

2 I, Amy M. Key, CSR, and Notary Public in
3 and for the County of Lamar, State of Mississippi,
4 hereby certify that the foregoing pages, under
5 penalty of perjury, contain a true and correct
6 transcript of the testimony of the witness, as
7 taken by me at the time and place heretofore
8 stated, and later reduced to typewritten form by
9 computer-aided transcription under my supervision
10 and to the best of my skill and ability.

11 I further certify that I placed the witness
12 under oath to truthfully answer the questions in
13 this matter under the power vested in me by the
14 State of Mississippi.

15 I further certify that I am not in the employ
16 of or related to any counsel or party in this
17 matter, and have no interest, monetary or
18 otherwise, in the final outcome of the
19 proceedings.

20 Witness my signature and seal this the
21 _____ day of _____, 2016.

22

23

AMY M. KEY, CSR

24 My Commission Expires June 19, 2016

25

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 0
- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 0
- 1
- 2
- 3
- 4
- 5

[illegible]

Subscribed and sworn
to before me this
_____ day of _____, 20____.
My commission expires:_____

Golkow Technologies, Inc.